

**TREATMENT JOURNEY OF SPINAL CORD STIMULATION  
SURGERY: AN INTERPRETATIVE PHENOMENOLOGICAL  
ANALYSIS**

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## **Thesis Abstract**

**Introduction:** This thesis explored Chronic Neuropathic Pain (CNP) patients' experiences of the treatment journey of Spinal Cord Stimulation (SCS) surgery, considering life prior to, and after the surgery. Previous SCS literature has predominantly focused on technology, SCS efficacy, and the role of psychological factors in SCS patient selection and outcomes. Whilst research highlights SCS as an effective treatment for various CNP conditions, it predominantly employs quantitative outcome measures, thereby reducing the depth of information yielded about the experience of SCS surgery and patient satisfaction. There is a dearth of in-depth understanding of the lived experience of the SCS surgery treatment journey.

**Objectives:** The aim of this thesis was to explore participant experiences of the SCS surgery treatment journey considering life prior to and after the surgery.

**Methods:** Ethical and NHS trust approval were obtained. A purposive sample of seven CNP patients who had undergone SCS surgery 2-8 months previously were recruited. Each participant took part in a face-to-face semi-structured interview which was audio recorded. Interviews were transcribed verbatim and analysed using Interpretative Phenomenological Analysis (IPA).

**Results:** Three super-ordinate themes were generated: Diminished control and coping, identity transitions and SCS conflict. The themes were interpreted as being interconnected with each other. To demonstrate the treatment journey, all themes were included in the journal paper and further details of convergences and divergences between participants were included in the extended paper.

**Discussion:** In line with previous research, patients' expectations of SCS surgery were significant in patient satisfaction with the outcomes, reinforcing the importance of identifying and addressing expectations in pre-surgery preparation. Given SCS is often the last treatment option; the current study found post-SCS participants were going through a process of acceptance of lost identities and of current pain relief and capabilities. Simultaneously, participants were adjusting to living with the stimulator, indicating the significance of offering psychological treatments adjunct to SCS treatment to support participants through these processes. Difficulties in acceptance of identity changes and adjustment to SCS could negatively impact on mood and sense of control which can have adverse effects on pain perception.

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## **Statement of Contribution**

### **1. Systematic review:**

Anna Turner (with supervision from Roshan das Nair, Jamie Macniven and Surajit Basu)

### **2. Research project design:**

Anna Turner (with supervision from Roshan das Nair, Jamie Macniven and Surajit Basu)

### **3. Applying for ethical approval:**

Anna Turner (with supervision from Roshan das Nair, Jamie Macniven and Surajit Basu)

### **4. Writing the thesis literature review:**

Anna Turner (with supervision from Roshan das Nair, Jamie Macniven and Surajit Basu)

### **5. Recruiting participants:**

Anna Turner arranged with the Consultant Neurosurgeon, Surajit Basu that the department of neurosurgery would disseminate the information packs

### **6. Data Collection:**

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### **7. Transcription:**

Anna Turner

### **8. Data Analysis:**

Anna Turner (with supervision from Roshan das Nair)

### **9. Write up of research project**

Anna Turner (with supervision from Roshan das Nair)

## Portfolio Contents

Systematic review	1
Research journal paper	34
Extended paper	65
Introduction	67
Method	83
Results	112
Discussion	134
Critical appraisal	151
References	158
Appendices	178
<b>Tables</b>	
<i>Systematic review</i>	
Table 1: Reliability and validity of measures	15
<i>Research project</i>	
Table 2: Interview schedule	41
Table 3: IPA analysis: Structure of themes	44
<b>Figures</b>	
Figure 1: Recruitment flow chart	94

## List of Appendices

<b>Appendix</b>	<b>Title</b>	<b>Page</b>
Appendix A	Common neuropathic pain conditions	179
Appendix B	Systematic reviews of SCS surgery	180
Appendix C	Search strategy	181
Appendix D	Data extraction pro-forma	182
Appendix E	Study characteristics	183
Appendix F	Key findings	189
Appendix G	Outcome measures in reviewed studies	193
Appendix H	Quality assessment criteria	196
Appendix I	Ethical approval letter	198
Appendix J	NHS trust approval letter	202
Appendix K	Cover letter	204
Appendix L	Patient information sheet	205
Appendix M	Minor amendment	213
Appendix N	Substantial amendment	217
Appendix O	Written consent	220
Appendix P	Demographic information sheet	221
Appendix Q	Study request form	222
Appendix R	Annual ethics report letter	223
Appendix S	Post interview reflections	224
Appendix T	Exploratory coding and diary extract	225
Appendix U	Identifying initial themes and diary extract	227
Appendix V	Numeration analysis	229
Appendix W	Theme table	230
Appendix X	Recurrent theme table	232
Appendix Y	Reflective diary extract: Organising themes	233

## **SYSTEMATIC REVIEW**



**A Systematic Review of Health Related Quality of Life following  
Spinal Cord Stimulation Surgery for patients with Chronic  
Neuropathic Pain<sup>1</sup>**

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<sup>1</sup> Systematic review for submission to 'Journal of Neurosurgery'

## **Abstract**

**Object.** To review Health Related Quality of Life (HRQoL) following Spinal Cord Stimulation (SCS) surgery as measured by generic HRQoL measures in chronic neuropathic pain patients.

**Methods.** Electronic databases and reference list searches were conducted to ascertain articles related to HRQoL following SCS surgery in patients experiencing chronic neuropathic pain. Two randomized controlled trials consisting of 7 studies and 2 case series were reviewed and assessed for methodological quality.

**Results.** SCS surgery resulted in significant pain reductions for Failed Back Surgery Syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS) patients. However, significant improvements in HRQoL that were sustained over time were restricted to FBSS patients.

**Conclusions.** SCS is effective at reducing neuropathic pain in FBSS and CRPS. However, more robust, long term trials, using a combination of generic and specific HRQoL measures are required to further understand the impact of SCS surgery on HRQoL with different neuropathic pain conditions.

**Key Words:** Spinal Cord Stimulation • Health Related Quality of Life • Outcomes • Chronic neuropathic pain • Systematic review

## **Introduction**

### **Chronic Neuropathic Pain (CNP)**

Neuropathic pain is initiated or caused by a primary lesion or dysfunction in the peripheral or central nervous system<sup>37</sup>. It is characterized by a constant burning pain, intermittent shooting pains and spontaneous paresthesias which manifests as abnormal sensations including numbness, itching and tingling<sup>14</sup>. It is termed chronic if the pain persists for at least 6 months, or if the symptoms last longer than would be expected for tissue healing<sup>36</sup>. Chronic pain has a negative impact on a person's quality of life (QoL) affecting their emotional, psychological, social and physical functioning<sup>44</sup>. It is a significant burden to health care systems and the worldwide economy<sup>8</sup>. The prevalence rates for neuropathic pain are estimated at 1-8% in the United Kingdom (UK)<sup>4,53</sup> and 1.5% in the United States<sup>4</sup>. CNP is most commonly located in the back and legs<sup>14</sup>. However, it is associated with a number of different medical conditions that are etiologically heterogeneous such as Failed Back Surgery Syndrome (FBSS), Complex Regional Pain Syndrome (CRPS) Type I and II, diabetic neuropathy, postherpetic neuralgia and spinal cord injury<sup>36</sup> (see appendix A for descriptions of conditions). There are a range of treatments for neuropathic pain including; anticonvulsants, antidepressants, oral medications with local anaesthetic properties, opioids, regional analgesics (injections to numb the painful area) and surgical procedures. Simple analgesics are ineffective for neuropathic pain<sup>18</sup>, this type of pain is termed intractable and individuals suffering from this are often offered more invasive treatments such as Spinal Cord Stimulation (SCS) surgery.

### **SCS**

The therapeutic application of electrical stimulation to the spinal cord has been used to treat various pain disorders since 1967, however advances in surgical techniques and technology have increased its popularity over recent years<sup>17</sup>. SCS involves surgically implanting a

small, battery powered stimulator into a patient. It delivers electricity to the spinal cord through an electrode which changes some of the pain messages the body sends to the brain<sup>51</sup>. Patients often undergo a trial electrical stimulation under local anaesthetic prior to the full implantation to determine whether effective pain relief of at least 50% is achieved<sup>12</sup>. Literature on the clinical effectiveness of SCS surgery demonstrates it is effective at reducing neuropathic pain as well as increasing quality of life, decreasing analgesic consumption and helping patients to return to work<sup>46</sup>. However, it is not effective for all types of pain; such as pain resulting from tissue damage, known as nociceptive pain<sup>43</sup> and pain due to insufficient blood flow for the metabolic needs of organs known as ischaemic pain<sup>44</sup>. In 2008, The National Institute of Health and Clinical Excellence (NICE) recommended SCS as a treatment option for CNP, however more robust research studies are required before recommending SCS for ischaemic pain<sup>38</sup>. This recommendation is likely to increase funding and opportunities for neuropathic patients to access this treatment in the UK.

SCS is associated with high costs; therefore evaluating cost effectiveness of the intervention has been a current focus in the literature<sup>3,47-49</sup>. Systematic reviews of cost effectiveness of SCS surgery report the initial high costs associated with the device implantation and the maintenance are offset by a reduction in the use of healthcare resources post implant<sup>47</sup>. Therefore, in the long term it is deemed less costly<sup>3</sup>.

Research suggests the presence and severity of CNP is associated with greater impairments in a number of important Health Related Quality of Life (HRQoL) domains including physical, emotional, and social functioning which impacts on life roles<sup>24</sup>. Therefore, cost effectiveness studies have examined costs in relation to HRQoL<sup>35</sup>. The evidence suggests the initial outlay costs of SCS surgery are

justified as there are substantial HRQoL gains in comparison to patients only receiving Conventional Medical Management (CMM) who experienced little or no benefits<sup>35</sup>.

### **Health related quality of life**

The term health related quality of life is used in many different contexts for a number of purposes resulting in there being no consensus of a definition<sup>41</sup>. Therefore, for the purpose of this article, health related quality of life will be understood in terms of the domains identified in a globally used standardised generic HRQoL measure. This is called the EQ-5D which was designed by the EuroQoL group<sup>1</sup>. In the development of the measure, authors drew on existing domains in HRQoL measures and consulted lay persons to ascertain appropriate terminology<sup>9</sup>. In this measure, HRQoL is understood in terms of an individual's mobility, their ability to carry out usual activities (work, study, housework, family, and leisure activities), their experience of pain/discomfort, feelings of depression/anxiety and self care (part of physical functioning<sup>21</sup>). Neuropathic pain patients have been noted to score considerably lower on the EQ-5D in comparison to other populations with severe illnesses such as chronic heart failure<sup>34</sup> and stroke<sup>35</sup>. This highlights the devastating impact of neuropathic pain. Evidence suggests SCS increases various aspects of HRQoL in many neuropathic pain conditions. Such evidence has identified improvements in activities of daily living and functioning in CRPS patients<sup>22</sup>, improvements in mood, activities and quality of sleep with patients with chronic back and extremity pain<sup>10</sup> and improvements in exercise tolerance in diabetic peripheral neuropathy<sup>50</sup>.

Research on SCS surgery employs either generic and/or specific measures when evaluating HRQoL. The latter refers to measures specifically designed to measure a disease/condition (e.g. diabetes/neuropathic pain); a population of patients (e.g. the elderly)

or a certain function (e.g. sleep, mobility). There are advantages and disadvantages of the use of both types of measures. Generic measures permit comparisons across interventions and different conditions and have been argued to be as responsive as disease specific measures<sup>40</sup>. Although, some authors propose specific measures are more sensitive to conditions<sup>21</sup>. Disease-specific measures have been criticised for trying to identify clinical information relevant to the condition rather than determine the impact of the condition on general function<sup>25</sup>. Furthermore, difficulties in interpreting batteries of measures have resulted in inaccurate conclusions about efficacy of treatment interventions<sup>40</sup>. For the purpose of this paper the focus will be on generic measures so direct comparisons can be made across different neuropathic pain conditions.

In conclusion, given the strong relationship between neuropathic pain severity and lower HRQoL and the improvements in HRQoL following SCS surgery, it seems pertinent to review the literature in this area. Previous reviews have included HRQoL when reviewing clinical effectiveness of SCS surgery; however they have failed to consider this important outcome independently, nor have they included recent evidence published since it was recommended as a treatment of choice for neuropathic pain<sup>38</sup>. The primary aim of this systematic review is to examine the evidence from available literature on HRQoL following SCS as evaluated by generic HRQoL measures. Pain intensity following SCS surgery as measured by Visual Analogue Scale (VAS) scores will also be included in the review because reducing neuropathic pain is the primary aim of SCS and higher levels of pain are associated with lower levels of HRQoL<sup>24</sup>.

## **Method**

### **Searching**

A systematic review of literature pertaining to HRQoL following SCS Surgery in neuropathic pain patients was conducted using six main electronic databases: Cochrane Library (1991 – July 2010), PsycInfo (1806 – July 2010), Medline (1950 – July 2010), EMBASE (1980 – July 2010), Intute (2006 – July 2010), and Web of Science (1900 – July 2010). Grey literature was searched using the electronic resources to reduce publication bias. The system for Information on Grey Literature in Europe (SIGLE) and DART-Europe Etheses and Dissertations were used. Searches were not restricted by language, date or publication type. The Cochrane Database of Systematic Reviews was used to identify recent systematic reviews conducted in this area. Furthermore, a scoping review was conducted using initial search terms to identify relevant systematic reviews on SCS surgery and neuropathic pain (see appendix B for reviews) and for generic HRQoL measures. From this information, more specific search terms were identified. Four primary search concepts were used, which covered the intervention, outcomes and population of interest: Spinal cord stimulation, QoL, outcomes, and neuropathic pain. Search terms for QoL were informed by terms used in generic HRQoL measures such as the EQ-5D, the Short Form-36 (SF-36)<sup>57</sup> and the Nottingham Health Profile (NHP)<sup>23</sup> as terminology in articles was observed to often correspond with these measures. An example of the MEDLINE search strategy is provided (see appendix C), which was modified for other databases. The scoping review demonstrated that very few HRQoL studies had been conducted for SCS surgery prior to the 1990's, with majority of clinical effectiveness studies only measuring pain outcomes, therefore hand searches were not completed.

Following electronic searches, 379 article's titles and abstracts were reviewed and 43 relevant articles retrieved. Reference lists from

systematic reviews and relevant articles were hand searched to identify a further 166 potentially relevant articles for abstract screening as titles tended not to specify whether HRQoL was measured. Duplicates were removed identifying 61 articles for further analysis, 42 of which were reviews. The inclusion and exclusion criteria were then applied (see below). There were 7 references from 2 trials accepted for the review and 2 case series. Although, these two trials were using the same participants, they were treated as separate studies as they were each investigating different hypotheses (e.g. SCS effectiveness at different time periods or a completely different hypothesis not related to SCS efficacy).

## **Selection**

### **Inclusion and exclusion criteria**

#### *Types of studies*

It is widely accepted that Random Controlled Trials (RCTs) are the 'gold standard' on the hierarchy of evidence for quality of study designs, followed by other controlled clinical trials and observational studies such as case series<sup>20</sup>. The initial scoping review of the literature revealed a range of methodological approaches in this area with few RCTs; therefore all of the above study designs were included to explore HRQoL following SCS surgery. Studies excluded were those at the bottom of the hierarchy such as single case studies, case reports or practice commentaries where results are difficult to generalise<sup>20</sup>. Studies were also excluded if they were; reviews or guidance papers that did not present original research; economic evaluations/ cost effectiveness articles and studies only published in languages that were not English.

#### *Intervention*

All SCS devices were included (e.g. rechargeable and non-rechargeable implantable pulse generator systems or stimulators with radiofrequency receiver systems). No restriction was imposed



on whether SCS was a single therapy or was used in combination with other therapies/medications. Studies were excluded when the neurostimulation intervention was on other parts of the nervous system such as deep brain stimulation.

### *Population*

Studies identifying their patient population as adults experiencing chronic neuropathic pain were included. Studies were excluded if participants were pregnant, children or in a chronic unconscious state (e.g. a long-term coma). Studies were also excluded if they failed to state participants' origin of pain as chronic neuropathic pain or if they did not specify that their pain met the classification criteria for a neuropathic pain condition. This was important as some syndromes (e.g. FBSS) can be the result of pain of different origins such as neuropathic and/or nociceptive<sup>44</sup>, and as previously stated SCS is less effective for nociceptive pain<sup>39</sup> which could bias HRQoL outcomes.

### *Outcomes*

Studies including a generic HRQoL measure to evaluate outcomes were included. Measures included in the review were required to meet the operational definition of HRQoL, which included covering areas similar to the following domains: mobility, pain, mood, activities and self care (i.e. functional abilities). Studies were excluded if they did not examine HRQoL.

A meta-analysis was not conducted due to the different methodologies employed. Therefore, the results will be presented descriptively.

## **Data abstraction**

Data was abstracted by using a standardised form modified from Torgerson<sup>52</sup> (see appendix D). A summary of the studies main characteristics is provided in appendix E and a summary of the key findings related to HRQoL and pain intensity is provided in appendix F. Although, not all of the outcome measures used in each study will be discussed to achieve the objectives of this review, descriptions of their function are provided to contextualise and synthesise the key findings (see appendix G). The quality of studies was assessed according to the criteria detailed in the NHS CRD Report No. 4<sup>29</sup> (see appendix H), with the aim of providing a descriptive account of the studies methodological quality. A numerical system was not employed. There is currently no 'gold standard' numerical scoring system for quality of studies<sup>31</sup> and there are inconsistencies in interpretation and application of criteria, which raises questions about the reliability and validity of such scoring in practice<sup>2</sup>.

## **Results**

In total, there were 4 studies from a Prospective Randomised Control Trial of Effectiveness of SCS (PROCESS)<sup>16,32-34</sup>, 3 studies from a Dutch prospective trial<sup>26-28</sup> and 2 case series<sup>45,56</sup>. The results section will be structured according to methodological design of the studies and information previously extracted in the tables.

## **RCTs**

### **General characteristics**

#### *Objectives*

All RCTs provided clear, specific objectives; five assessed the efficacy of SCS as a treatment for neuropathic pain compared with a control group. Follow ups ranged from 6-60 months. In contrast, study A3 used the PROCESS trial data to assess the extent to which disease-specific measures on pain and disability translated to improvements in HRQoL on generic measures. Lastly, study A4 used

the PROCESS data to analyse the sub-dimensions of both the disease-specific and generic HRQoL measures.

### *Participants*

Sample sizes ranged from 54-100 participants. Both sets of trials included basic participant demographics such as average age, gender, and information on pain type, location, and treatment history. However, neither trial provided age ranges, ethnicity or marital status. Kemler and colleagues<sup>26-28</sup> did not specify employment status. Age and gender were specified for both the intervention and control groups in both trials at baseline, however at follow up when numbers depleted changes in demographic data were not detailed in study B6 and B7.

The PROCESS trial employed FBSS patients with neuropathic pain of radicular origin, which was predominantly located in the leg (exceeding back pain). The nature of the neuropathic pain was checked as per routine practice through clinical investigations and supporting tests such as X-ray and Magnetic Reasoning Imagery (MRI). In contrast, the Kemler trial failed to identify whether such procedures had been completed, but stated all patients met the diagnostic criteria for Reflex Sympathetic Dystrophy (RSD) established by the International Association for the study of Pain<sup>37</sup>. RSD is now more commonly referred to as Complex Regional Pain Syndrome (CRPS) type I, which is the term used in the last paper of the trial.

### *Setting, country and treatment period*

Both trials provided details of participant recruitment and the treatment period. The Kemler trial recruited participants from the authors neurosurgery department, a single site in the Netherlands, whereas the PROCESS trial recruited from 12 sites based in Australia, Belgium, Canada, Israel, Italy, Spain, Switzerland, and the

UK. The PROCESS trial did not provide specific percentages of participants from each country.

### *Study design*

Both were prospective RCTs and eligible patients were required to have a pain intensity VAS score of at least 50mm (5cm). In line with the literature suggesting psychological factors can negatively impact on SCS efficacy<sup>12</sup>, the Kemler trial also screened for psychological distress using the Symptom Check List-90 (SCL-90). Any SCL-90 scores of 200 or more resulted in further examination by a psychologist. Any substance abuse or major psychiatric diagnosis excluded participants from the trial. Conversely, the PROCESS trials did not screen for psychological distress but noted patients with evidence of an active psychiatric disorder were excluded.

Test stimulation was performed in both trials. Effectiveness was judged by patients achieving at least a 50% reduction in pain intensity on the VAS. In the Kemler trial no participants failing test stimulation were implanted, however five of the nine participants (17%) who failed test stimulation in the PROCESS trial received permanent implants.

As evident in the study characteristics (appendix E), there was heterogeneity in comparators. The PROCESS trial used SCS and CMM as the intervention, and CMM alone as the comparator. CMM consisted of using oral medication (such as opioids, non-steroidal anti-inflammatory drugs, antidepressant, anti-convulsants/antiepileptic and other analgesic therapies), nerve blocks, epidural corticosteroids, physical and psychological rehabilitative therapy, and/or chiropractic care. In contrast, Kemler et al employed SCS and Physical Therapy (PT) as the intervention and PT alone as the comparator. The PT was a standardised program of graded exercises which aimed to improve strength, mobility, and function of

the affected hand or foot. The therapy was administered for 30 minutes, twice a week, with a minimum of two days between sessions. The program lasted for six months. Selected physical therapists were specifically trained to run the program to ensure standardisation.

#### *Outcome measures*

Both trials measured HRQoL as a secondary outcome to pain, employing both generic and specific measures to form a battery of tests. Sub-dimensions of the measures were intermittently reported. Both trials employed VAS scores to quantify pain and used the EQ-5D as a generic HRQoL measure. However, study A1 did not report EQ-5D results with no explanation of why this was omitted from the 6 months analysis. The SF-36, EQ-5D and NHP met the operational definition for HRQoL as generic measures; however the Sickness Impact Profile (SIP) did not due to lacking a pain scale. Furthermore, authors note this is to be used with a battery of other measures, not in isolation<sup>19</sup>. Other measures employed varied across trials (a description of all measure employed in the studies has been included in appendix G). There were numerous studies investigating the reliability and validity of the generic HRQoL measures (see Table 1); however estimates for a neuropathic pain population could not be located. Results were inconsistent, but generally showed adequate reliability and validity other than for VAS for chronic pain; however this study had an extremely small sample size.

TABLE 1  
*Reliability and Validity of Measures*

Outcome Measure	Type of Measure	Reliability	Validity
Visual Analogue Scale (VAS) <sup>11,42</sup>	Pain	By averaging responses from three 100mm VAS pain ratings assessing current, average and worse pain, it is suggested adequate internal consistency was gained (alpha coefficient 0.77). It was more normally distributed than individual VAS scores in a sample of 320 individuals with temporomandibular disorder (TMD) pain <sup>15</sup> .	Validity estimates for VAS have been reported as unsatisfactory for chronic pain <sup>11</sup> . However, this was based on an extremely small sample.
Nottingham Health Profile (NHP) <sup>23</sup>	HRQoL	Test-retest reliability on a group of patients with PVD <sup>2</sup> suggested high correlation co-efficients for sub-dimensions of both parts of the questionnaire: Spearman's Rho ranging between, $r = 0.75-0.88$ ( $p < 0.01$ ). Part two = Cramers $\phi$ ranging between $\phi = 0.55-0.89$ ( $p < 0.01$ ) <sup>23</sup> .	Face, content and criterion validity were reported to be satisfactory and the measure was able to discriminate between ill and well people <sup>5</sup> .

<sup>2</sup> = Peripheral Vascular Disease (PVD)

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EuroQoL 5D (EQ-5D) <sup>30</sup>	HRQoL	Test re-test reliability for the five domains has been calculated using a Kappa co-efficient in a group of stroke patients. Results suggested co-efficients between 0.63-0.80 <sup>13</sup> .	Validation in a neuropathic pain population could not be found. However, construct validity has been reported in a number of clinical applications <sup>13</sup> . Some support for its convergent validity was obtained when comparing the EQ-5D to the SF-6D across a range of patients group; however a number of discrepancies were also identified across the patient group and severity of illness <sup>6</sup> .
Short Form 36 (SF36) <sup>57</sup>	HRQoL	Studies estimate each scale reliability co-efficients as exceeding a median of 0.76.	SF-36 is suggested to include 8 of the most frequently

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<p>Internal consistency estimates of the 8 scales ranged from 0.73 to 0.96 and test re-test reliability estimates on the 8 scales ranged from 0.60 to 0.81<sup>7</sup></p>	<p>presented health concepts<sup>58</sup>.</p> <p>Weak to strong correlations have been reported between the SF-26 and other measures.</p> <p>Strong correlations were obtained between the physical functioning subscale of the SIP, the AIMS and the NHP (0.52 to 0.85) and strong correlations were reported between the mental health sub-scales of the SF-36 and other psychological subscales (ranging from <math>r=0.51</math> to <math>r=0.82</math>)<sup>5</sup>.</p>
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Statistical analyses were identified in both trials and data was provided on participants treatment allocation as opposed to the actual treatment received in line with the Intention-to-treat (ITT) principle. Both trials reported per treatment analyses, which is the actual treatment received. Both trial employed independent t-tests to compare baseline data between groups and study B5 used non-parametric tests when data was not normally distributed. Both used different types of multivariate regressions/logistic regressions (depending on if data was continuous or dichotomous) to assess the potential influences of baseline differences between the groups and outcome variables on the size of treatment effects.

#### *Follow ups*

Details of withdrawals and losses at follow ups were explicitly stated in both trials and at least 80% of the samples were retained at the 6 month follow up. However, at 24 months study A2 retained approximately 50% and study B6 retained approximately 70% of their sample.

### **Key findings**

Primary pain outcomes as measured by VAS scores and HRQoL evaluated by generic measures are presented (see appendix F).

Both trials suggest SCS surgery was effective at achieving at least 50% pain relief at 6 months and provided more pain relief in comparison to the control group. Study A1 showed significantly greater reduction in leg pain ( $p<0.001$ ) and back pain ( $p<0.008$ ) compared with CMM alone and study B5 showed significant reduction in pain in the SCS group, whereas the PT alone group mean scores increased (SCS = decreased by 2.4, PT increased by 0.2,  $p<0.001$ ).

Improvements in HRQoL as measured by generic HRQoL measures varied across the two neuropathic pain conditions (FBSS and CRPS). At 6 months, the PROCESS trial which employed FBSS patients showed significant improvements on HRQoL on seven of the eight SF-36 domains excluding 'role-emotional' (mean = 51.3,  $p=0.02$ ). Whereas the CMM group only achieved significant improvement on the General Health domain of the SF-36 (mean = 41.3,  $p<0.007$ ). Significant differences between groups were obtained in seven out of the eight domains  $p\leq 0.02$ , however not in the 'role-physical' domain.

In contrast, the Kemler trial ITT analysis on CRPS patients at 6 months showed no differences between SCS + Physical Therapy (PT) group on HRQoL as measured by the NHP and EQ-5D. Therefore, no values were presented. However, per treatment received analyses (PTRA) showed the SCS group ( $n=24$ ) experienced significant improvements in comparison to the PT group on the pain index of the NHP, for patients with hand ( $p=0.02$ ) and foot ( $p=0.008$ ) pain. The results from the two generic HRQoL measures (EQ-5D and NHP) and the specific measures (SIP and SRDS) were not presented; one value of HRQoL was tabulated. It is unclear how this single value was calculated from these measures.

At 24 months, study A2 completed a comparison with baseline results showing the SCS+CMM group reported significant reductions in leg pain ( $p<0.0001$ ), but not back pain ( $p=0.21$ ). Study B5 did not report within group comparisons, however found the SCS and PT group reported more pain reductions than the PT alone group (SCS+PT = 2.1cm, PT alone = 0cm,  $p<0.01$ ).

The variations in HRQoL results between the different neuropathic pain patients employed in each trial were sustained at 24 months. When compared with baseline results, study A2 SCS+CMM group

again reported improvements on seven out of the eight domains of the SF-36 ( $p \leq 0.01$ ), apart from the role emotion domain ( $p = 0.11$ ). In contrast, study B6 reported no within group data and there were still no significant differences between groups.

There were inconsistencies across the studies in whether or not they reported the sub-dimensions of the generic HRQoL measures. Although all 9 studies used the EQ-5D as a generic HRQoL measure, only study A4 drawing on the PROCESS Trial data to specifically analyse the sub-dimensions of the measures presented the sub dimensions of the EQ-5D.

In studies where the sub-dimensions were presented (A1&2 = SF-36, A4 = SF-36 & EQ-5D, B5&6 = NHP), they highlight the relationship between the level of pain and the patient's perception of their HRQoL. Studies B5 and B6 demonstrated improvements in HRQoL were indicated by the pain dimension of the NHP at 6 and 24 months. Study A3 demonstrated higher levels of pain and disability was associated with lower level of quality of life. Likewise, study A4 highlighted a proportion of patients still experiencing HRQoL problems were related to pain and discomfort, with 34% reporting extreme pain problems.

At 6 months, study A4 indicated the SCS group showed greater scores on the physical component summary (PCS) and mental component summary (MCS) of the SF-36 (PCS mean = 32.4, MCS mean = 44.5) in comparison to the CMM alone group (PCS mean = 28.1, MCS = 37.7). Significant improvements were evident from baseline till the 24 months follow up ( $p \leq 0.01$ ). The SCS group also showed greater improvements compared to baseline and the CMM alone group on 4 of the 5 dimensions of the EQ-5D (not mobility) which was also sustained over 24 months.

### **Quality and methodological issues**

Both trials completed baseline assessments prior to randomisation and detailed adequate randomisation assignment using computer generated tables<sup>32</sup> or blocks<sup>26</sup>. Both concealed the randomisation process from investigators one trial by electronically locking details until the patient entered the trial<sup>32</sup> and the other via telephone by a research assistant stating the number of patients randomised<sup>26</sup> (see appendix H). Due to the paresthesia that accompanies stimulation, patients were not blinded and it was difficult to blind investigators. Therefore, this cannot rule out the risk of a placebo effect, which is noted to be highly prevalent amongst surgical procedures<sup>55</sup>. Authors in both trials argue the consistency of pain relief across 1, 3, & 6 months follow up suggest the results are not due to a placebo response<sup>26</sup>.

Baseline characteristics of the intervention and control groups in both trials were comparable, excluding back pain in the PROCESS trial which was slightly higher in the control group. Although, authors argue leg pain is the primary outcome where no differences were evident, this cannot rule out the potential effects of greater back pain on the controls responses in other measures such as the HRQoL questionnaires given the evidence suggesting neuropathic pain severity is associated with lower HRQoL<sup>24</sup>.

Although using a homogenous population is desirable when employing questionnaires to measure outcomes, as demonstrated there appears to be specific differences in HRQoL after SCS surgery between neuropathic pain conditions. Therefore, this limits the generalisability of the results to patients where the predominant neuropathic pain is located in other areas and other pain conditions.

Participants recruited in the Kemler study were severely disabled, many of whom required crutches or wheelchairs to move, and

therefore the impact on HRQoL may have been very different with patients in the earlier stages of the condition.

The neurostimulators used in the PROCESS trial were provided by the company Medtronic who funded the trial. The trial was designed and managed by a committee that included four external representatives and two from Medtronic and the manuscript was written by the independent members of the committee. Research suggests industry funded studies report more favourable results than independent studies<sup>54</sup>.

## **Case series**

### **General characteristics**

#### *Objectives*

Study 8 specified a specific primary and secondary objective, to ascertain if patients could use the neurostimulator and evaluation of clinical effectiveness of SCS on a range of outcome measures. However, study 9 failed to state an objective in the abstract or the main text. Authors stated a goal 'to build a quality system for neuromodulation' (p.185), which is broad and unclear.

#### *Participants*

Sample sizes ranged from 45-105 participants. Both case series included basic participant demographics such as average age, gender, and information on pain type, location, and treatment history. Unlike the RCTs, they both included average pain duration (study 8 = 86 months; study 9 = 134 months) and Study 9 included an age range (31.1 to 69.4 years). However, again neither study provided ethnicity or marital status and only Study 9 included employment details. Changes in demographics after drop outs and withdrawals were not recorded in either study.

Similar to the RCTs, both studies employed representative samples of common neuropathic pain conditions. Study 8 employed patients of mixed diagnoses, predominantly post-operative back or leg pain (55%); radicular pain (27%) and CRPS type I (7%) and type II (7%). However, authors referred to the last 4% as 'other'. Therefore, it is unclear what type of neuropathic pain the remaining participants experienced. Study 9 recruited FBSS patients with predominantly Neuropathic Limb Pain (NLP) Type III which manifests in one leg with some back pain (87.6%) and NLP Type II, which manifests only in the leg (12.4%).

#### *Setting, country and treatment period*

Study 8 provided limited details of participant recruitment and the study settings. It reported it was a multicentre study with participants recruited from 12 sites, however failed to specify the specific countries and percentages of how many participants came from each site. In contrast, study 9 stated it was undertaken in the Netherlands. Both studies stated the study treatment period, which meant all studies reviewed stated this information.

#### *Study design*

Study 9 eligibility criteria identified only patients with pain intensity VAS score of 5 or above and employed the SCL-90 checklist to screen psychological distress (scores 225 or above). In contrast, study 8 did not provide a VAS cut off score nor did they screen for psychological factors. The study provided limited exclusion criteria without mentioning whether patients with psychiatric disorders were accepted into the study.

Test stimulation was performed in both studies. In contrast to all other studies in this review, study 8 did not use the 50% pain intensity reduction as a judge of effectiveness. Instead effectiveness was judged by patient and physician satisfaction.

### *Outcome measures*

Both studies employed outcome measures for the patient to provide evaluation of their experience; however study 8 included the physician's satisfaction of the stimulator also. Both studies employed generic and specific HRQoL measures, which were different but covered similar constructs appropriate for the pain condition (functionality, pain and HRQoL). Both used the EQ-5D.

Statistical analyses employed to compare baseline scores to follow up were different in studies 8 and 9. Study 8 used t-tests to compare VAS and the EQ-5D data, whereas study 9 used a non-parametric test the Wilcoxon Signed rank Test.

### *Follow ups*

Both studies had a 12 month follow up and clearly identified changes in sample size and reasons for participant leaving or being excluded from the study.

## **Key findings**

Primary pain outcomes as measured by VAS scores and HRQoL evaluated by generic measures are presented (see appendix F).

Following SCS treatment both studies showed significant and similar improvements in pain from baseline to the 12 months follow up (study 8 = 7.2 to 4.4, study 9 = 7.3 to 3.0).

Both studies indicate significant improvements in HRQoL as measured by the EQ-5D. Study 8 showed a mean increase in VAS scores from 0.21 to 0.46 at 12 months. Study 9 showed a mean decrease from 55.2 to 38.2 using the same measure. As evident from the scores, both studies employed a different method to calculate the scores that is not consistent with the user guide. There are a number of ways to score the EQ-5D, however there are relevant papers

identifying these methods that can be referenced. Although, Study 9 acknowledges not following the user guide, it does not refer the reader to the scoring system adopted or explain it. This lack of consistency in scoring makes it difficult to make accurate comparisons between studies.

### **Quality and methodological issues**

Both studies included an inclusion and exclusion criteria, although study 8 only briefly states participants were required to be adults, meet a neuropathic pain condition criteria and were excluded if they had previously been implanted with an SCS system. It failed to clarify what other treatment patients implanted were undergoing at the time of evaluation and whether individuals with psychiatric disorders were excluded.

Neither study explicitly specified whether patients were entered into the study at a similar point in their condition progression; however this would have been difficult for Study 8 with the mixed diagnoses. Both studies completed 12 months follow ups therefore allowing sufficient time before evaluating the impact of SCS on levels of pain and HRQoL.

In the discussion of study 9, it provided comparisons of results with a study completed by Burchiel et al<sup>10</sup> which demonstrated comparable results. However, no explicit conclusions were stated about outcomes of pain and HRQoL used in the study.



## Discussion

The aim of this review was to systematically examine the literature on HRQoL as measured by generic measures after SCS surgery. Pain relief as measured by VAS scores was also considered in this review due to this being the primary aim of SCS to reduce neuropathic pain and the strong relationship between neuropathic pain severity and lower levels of HRQoL previously identified<sup>24</sup>. The literature reviewed suggests that SCS results in improvements in pain relief and HRQoL as measured by generic measures. However, there are distinct differences between pain conditions and whether changes are sustained over time.

Improvements in pain intensity as measured by VAS scores were evident in both FBSS and CRPS patients. However, improvements in HRQoL were only demonstrated in FBSS patients. FBSS patients scores on HRQoL generic measures improved when compared to baseline and a CMM alone control group. These results were sustained at 6 months (study A1), 12 months (study 9) and 24 months (study A2). When the measures were broken down into component parts, improvements were evident across all domains of the SF-36 and EQ-5D apart from mobility (study A4). Results generally highlighted the significance impact of pain on individuals HRQoL which supports previous research<sup>24</sup>.

Conversely, the Kemler RCT demonstrated no significant changes in HRQoL in patients with CRPS and improvements were not sustained over time. However, study 8 results showed improvements in HRQoL with their sample which included CRPS patients. Additionally, other prospective clinical studies that employed CRPS patients with severe disabilities found significant improvements in pain intensity and HRQoL using different more specific measures of functionality, activities of daily living and pain<sup>22</sup>. Although the quality of these studies was lower than the Kemler RCTs, it highlights that using

different measures can yield different results for the same conditions. Of note, despite the Kemler trial not achieving statistically significant gains in HRQoL through outcome measures, patient satisfaction suggested 90% felt they had responded positively to the treatment and 95% reported they would undergo the treatment again with the same outcomes. This contrast in statistical results from self report measures and reported satisfaction reinforces the importance of establishing more robust measurements of HRQoL.

### *Clinical implications*

Neuropathic pain is a severe, chronic condition resistant to regular treatment<sup>18</sup> which is associated with high costs for health services across the globe<sup>8</sup>. Therefore, a strong clinical implication is providing an effective treatment that decreases pain and increases HRQoL to avoid economic burden. As previously identified, the initial outlay cost of SCS surgery are reported to be justified by the reduction of health resources consumption post implant making it a desirable treatment option both economically and clinically due to the HRQoL gains for certain neuropathic pain patients. However, only one study appears thus far to have investigated the relationship between HRQoL, cost and resource consumption at 6 months follow up; therefore further longer term research is required. A combination of the NICE recommendations and extra cost effectiveness research could provide more opportunities for this hard to treat patient group to access SCS surgery.

### *Limitations*

Although rigorous methods were undertaken to reduce bias, this review is not without limitations. The search terms used may not have been broad enough, particularly for neuropathic pain. This was kept generic in order to prevent restricting the search to specific neuropathic pain conditions, however specifying a range of conditions as search terms may have resulted in more articles. A

further limitation is failing to examine specific measures of different aspects of HRQoL that formed a battery of tests. The current results indicate it is becoming more common practice for clinical studies to employ both generic and specific measures to produce more comprehensive results, which is important in light of growing evidence suggesting different measures of HRQoL are differentially sensitive to effects of neuropathic pain<sup>24</sup>.

### *Future research*

Therefore, future systematic reviews could consider a two-tier review using generic and specific measures to examine HRQoL after SCS surgery. Furthermore, more robust, high quality, long term RCTs are required in the various neuropathic pain conditions before generating conclusions about HRQoL after SCS surgery, especially its effectiveness over time. There is a distinct lack of consistency in the measures employed in studies, how measures are scored, and how results are interpreted and presented. It is imperative that consistency is achieved to create a stronger, higher quality body of evidence for this difficult to treat patient group whose quality of life is so poor.

Furthermore, this review highlighted the dearth in the literature of any in depth qualitative studies exploring the patient's experience of pain and HRQoL following SCS surgery. Categorising outcomes has been suggested as over-simplistic given that pain can vary over time, place and circumstances<sup>43</sup>, which is also likely to impact on an individual's quality of life. Therefore, future qualitative studies should be conducted to complement the existing evidence base.

In conclusion, the quality and quantity of quantitative SCS research is growing. Evidence suggests that most HRQoL domains improve following SCS surgery in certain neuropathic pain conditions such as FBSS which can be sustained over time. However, it highlighted that

CRPS patients with more severe functional difficulties have not consistently achieved the same HRQoL gains. Therefore, further more robust studies are required in CRPS and other neuropathic pain conditions. It is important that a variety of specific and generic measures are employed to provide a more comprehensive and sensitive battery of measures. Furthermore, other methodologies such as qualitative studies could provide more breadth and depth to the existing literature.

## References

1. EuroQol--a new facility for the measurement of health-related quality of life. The EuroQol Group. **Health Policy** **16**:199-208, 1990
2. Atkins D, Eccles M, Flottorp S, Guyatt GH, Henry D, Hill S, et al: Systems for grading the quality of evidence and the strength of recommendations - I: Critical appraisal of existing approaches The GRADE Working Group. **BMC Health Services Research** **4**, 2004
3. Bala MM, Riemsma RP, Nixon J, Kleijnen J: Systematic Review of the Cost-effectiveness of Spinal Cord Stimulation for People With Failed Back Surgery Syndrome. **Clinical Journal of Pain** **24**:741-756, 2008
4. Bennett GJ: Neuropathic pain: new insights, new interventions. **Hosp Pract (Minneap)** **33**:95-98, 101-104, 107-110 passim, 1998
5. Bowling A: **Measuring Health: A review of quality of life measurement scales, ed 2nd**. Buckingham: Open University Press, 1991
6. Brazier J, Roberts J, Tsuchiya A, Busschbach J: A comparison of the EQ-5D and SF-6D across seven patient groups. **Health Econ** **13**:873-884, 2004
7. Brazier JE, Harper R, Jones NM, O'Cathain A, Thomas KJ, Usherwood T, et al: Validating the SF-36 health survey questionnaire: new outcome measure for primary care. **BMJ** **305**:160-164, 1992
8. Brook AL, Georgy BA, Olan WJ: Spinal cord stimulation: a basic approach. **Tech Vasc Interv Radiol** **12**:64-70, 2009
9. Brooks R: EuroQol: the current state of play. **Health Policy** **37**:53-72, 1996
10. Burchiel KJ, Anderson VC, Brown FD, Fessler RG, Friedman WA, Pelofsky S, et al: Prospective, multicenter study of spinal cord stimulation for relief of chronic back and extremity pain. **Spine (Phila Pa 1976)** **21**:2786-2794, 1996
11. Carlsson AM: Assessment of chronic pain. I. Aspects of the reliability and validity of the visual analogue scale. **Pain** **16**:87-101, 1983
12. Doleys DM: Psychological factors in spinal cord stimulation therapy: brief review and discussion. **Neurosurg Focus** **21**:E1, 2006
13. Dorman P, Slattery J, Farrell B, Dennis M, Sandercock P: Qualitative comparison of the reliability of health status assessments with the EuroQol and SF-36 questionnaires after stroke. United Kingdom Collaborators in the International Stroke Trial. **Stroke** **29**:63-68, 1998
14. Dworkin RH, Backonja M, Rowbotham MC, Allen RR, Argoff CR, Bennett GJ, et al: Advances in neuropathic pain - Diagnosis, mechanisms, and treatment recommendations. **Archives of Neurology** **60**:1524-1534, 2003

15. Dworkin SF, Von Korff M, Whitney CW, Le Resche L, Dicker BG, Barlow W: Measurement of characteristic pain intensity in field research. **Pain** **41**:S290-S290, 1990
16. Eldabe S, Kumar K, Buchser E, Taylor RS: An Analysis of the Components of Pain, Function, and Health-Related Quality of Life in Patients with Failed Back Surgery Syndrome Treated with Spinal Cord Stimulation or Conventional Medical Management. **Neuromodulation** **13**:201-209, 2010
17. Falowski S, Celii A, Sharan A: Spinal cord stimulation: An update. **Neurotherapeutics** **5**:86-99, 2008
18. Gilron I, Watson CP, Cahill CM, Moulin DE: Neuropathic pain: a practical guide for the clinician. **CMAJ** **175**:265-275, 2006
19. Gilson BS, Gilson JS, Bergner M, Bobbit RA, Kressel S, Pollard WE, et al: The sickness impact profile. Development of an outcome measure of health care. **Am J Public Health** **65**:1304-1310, 1975
20. Greenhalgh T: **How to read a paper: the basics of evidence-based medicine**, ed 3rd Massachusetts: Blackwell Publishing, 1997
21. Guyatt GH, Feeny DH, Patrick DL: Measuring health-related quality of life. **Ann Intern Med** **118**:622-629, 1993
22. Harke H, Gredenkort P, Ladleif HU, Rahman S: Spinal cord stimulation in sympathetically maintained complex regional pain syndrome type I with severe disability. A prospective clinical study. **European Journal of Pain** **9**:363-373, 2005
23. Hunt SM, McEwen J, McKenna SP: Measuring health status: a new tool for clinicians and epidemiologists. **J R Coll Gen Pract** **35**:185-188, 1985
24. Jensen MP, Chodroff MJ, Dworkin RH: The impact of neuropathic pain on health-related quality of life - Review and implications. **Neurology** **68**:1178-1182, 2007
25. Kaplan RM, Anderson JP, Wu AW, Mathews WC, Kozin F, Orenstein D: The Quality of Well-Being Scale - Applications in Aids, Cystic-Fibrosis, and Arthritis. **Medical Care** **27**:S27-S43, 1989
26. Kemler MA, Barendse GA, van Kleef M, de Vet HC, Rijks CP, Furnee CA, et al: Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. **N Engl J Med** **343**:618-624, 2000
27. Kemler MA, de Vet HC, Barendse GA, van den Wildenberg FA, van Kleef M: Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial. **J Neurosurg** **108**:292-298, 2008
28. Kemler MA, De Vet HC, Barendse GA, Van Den Wildenberg FA, Van Kleef M: The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. **Ann Neurol** **55**:13-18, 2004

29. Khan K: Undertaking systematic reviews of research on effectiveness CRD's guidance for those carrying out or commissioning reviews. 2001
30. Kind P: The EuroQoL instrument: an index of health-related quality of life. **Quality of life and pharmacoeconomics in clinical trials**:191-201, 1996
31. Knipschild P: Searching for alternatives: loser pays. **Lancet** **341**:1135-1136, 1993
32. Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, et al: Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomised controlled trial in patients with failed back surgery syndrome. **Pain** **132**:179-188, 2007
33. Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, et al: The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. **Neurosurgery** **63**:762-768, 2008
34. Manca A, Eldabe S, Buchser E, Kumar K, Taylor RS: Relationship between Health-Related Quality of Life, Pain, and Functional Disability in Neuropathic Pain Patients with Failed Back Surgery Syndrome. **Value in Health** **13**:95-102, 2010
35. Manca A, Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, et al: Quality of life, resource consumption and costs of spinal cord stimulation versus conventional medical management in neuropathic pain patients with failed back surgery syndrome (PROCESS trial). **European Journal of Pain** **12**:1047-1058, 2008
36. Medical Advisory Secretariat: Spinal cord stimulation for neuropathic pain: an evidencebased analysis. **Ontario Health Technology Assessment Series** **5**:1-78, 2005
37. Merskey H, Bogduk N: Classification of chronic pain: descriptions of chronic pain syndromes and definitions of pain terms. 1994
38. National Institute of Health and Clinical Excellence: Spinal Cord Stimulation for chronic pain of neuropathic or ischaemic origin, in **NICE technology appraisal guidance 159**: NHS, 2008, pp 1-36
39. North R, Kidd D, Zahurak M, James C, Long D: Spinal cord stimulation for chronic, intractable pain: experience over two decades. **Neurosurgery** **32**:384, 1993
40. O'Connor R: **Measuring quality of life in health**: Churchill Livingstone, Edinburgh, 2004
41. Phillips D: **Quality of life: concept, policy and practice**: Routledge, 2006
42. Scott J, Huskisson E: Graphic representation of pain. **Pain** **2**:175-184, 1976
43. Simpson B: Spinal cord stimulation. **British Journal of Neurosurgery** **11**:5-11, 1997

44. Simpson EL, Duenas A, Holmes MW, Papaioannou D, Chilcott J: Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. **Health Technol Assess** **13**:iii, ix-x, 1-154, 2009
45. Spincemaille GH, Beersen N, Dekkers MA, Theuvenet PJ: Neuropathic limb pain and spinal cord stimulation: Results of the Dutch prospective study. **Neuromodulation** **7**:184-192, 2004
46. Taylor RS: Spinal cord stimulation in complex regional pain syndrome and refractory neuropathic back and leg pain/failed back surgery syndrome: results of a systematic review and meta-analysis. **J Pain Symptom Manage** **31**:S13-19, 2006
47. Taylor RS, Taylor RJ, Van Buyten JP, Buchser E, North R, Bayliss S: The cost effectiveness of spinal cord stimulation in the treatment of pain: a systematic review of the literature. **J Pain Symptom Manage** **27**:370-378, 2004
48. Taylor RS, Van Buyten JP, Buchser E: Spinal cord stimulation for chronic back and leg pain and failed back surgery syndrome: A systematic review and analysis of prognostic factors. **Spine** **30**:152-160, 2005
49. Taylor RS, Van Buyten JP, Buchser E: Spinal cord stimulation for complex regional pain syndrome: a systematic review of the clinical and cost-effectiveness literature and assessment of prognostic factors. **Eur J Pain** **10**:91-101, 2006
50. Tesfaye S, Watt J, Benbow SJ, Pang KA, Miles J, MacFarlane IA: Electrical spinal-cord stimulation for painful diabetic peripheral neuropathy. **Lancet** **348**:1698-1701, 1996
51. The British Pain Society: Spinal cord stimulation for pain: Information for patients. **The British Pain Society** 1-12, 2005
52. Torgerson C: **Systematic reviews**: Continuum International Publishing Group, 2003
53. Torrance N, Smith BH, Bennett MI, Lee AJ: The epidemiology of chronic pain of predominantly neuropathic origin. Results from a general population survey. **J Pain** **7**:281-289, 2006
54. Turner JA, Deyo RA, Loeser JD: Spinal cord stimulation: Stimulating questions. **Pain** **132**:10-11, 2007
55. Turner JA, Deyo RA, Loeser JD, Vonkorff M, Fordyce WE: The Importance of Placebo-Effects in Pain Treatment and Research. **Jama-Journal of the American Medical Association** **271**:1609-1614, 1994
56. Van Buyten JP, Fowo S, Spincemaille GH, Tronnier V, Beute G, Pallare JJ, et al: The restore rechargeable, implantable neurostimulator: Handling and clinical results of a Multicenter study. **Clinical Journal of Pain** **24**:325-334, 2008
57. Ware J: **SF-36 health survey: manual and interpretation guide**: The Health Institute, New England Medical Center, 1993
58. Ware Jr JE, Gandek B: Overview of the SF-36 Health Survey and the International Quality of Life Assessment (IQOLA) Project. **Journal of Clinical Epidemiology** **51**:903-912, 1998



## JOURNAL PAPER

**Treatment Journey of Spinal Cord Stimulation Surgery:  
An Interpretative Phenomenological Analysis<sup>3</sup>**

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## **Abstract**

**Object.** Existing research has focused on spinal cord stimulation (SCS) efficacy, technology, and patient selection and suitability. In contrast, this study aimed to explore the lived experience of the treatment journey of SCS, with regard to how patients made sense of their life of chronic neuropathic pain prior to, and following, the SCS implant.

**Methods.** The study employed a qualitative methodology. Seven participants were interviewed face-to-face using a semi-structured interview schedule. These were digitally audio-recorded and transcribed verbatim. The transcripts were then analysed using Interpretative Phenomenological Analysis.

**Results.** Three super-ordinate themes were generated from the analysis: diminished control and coping, identity transitions and SCS conflict.

**Conclusions.** In line with past research, patient expectations appeared to impact on SCS treatment satisfaction, reinforcing the importance of addressing these in pre-surgery preparation. The study provides novel insights into the experience of accessing SCS. It highlights that emotional support may be useful for those experiencing complications in obtaining their SCS to reduce feelings of powerlessness. Also, as SCS was often the last treatment option, these participants described a process of acceptance of their lost identities, levels of pain relief and current capabilities. Simultaneously, participants were adjusting to the presence of the stimulator and living with the device. Therefore, post-surgical psychological support could be offered in conjunction with SCS to assist in coping with these processes. Increasing acceptance of identity changes and adjustment to SCS could positively impact on mood, pain perception and subsequent SCS treatment satisfaction.

**Key words • Spinal cord stimulation • Chronic neuropathic pain • Patient perspective • Qualitative research • Interpretative phenomenological analysis • Lived experience**

## Introduction

Neuropathic pain (NP) is caused by a primary lesion or dysfunction in the nervous system<sup>24</sup> and is one of the most challenging conditions to treat in neurological practice<sup>32</sup>. It is termed chronic if the pain persists for at least six months, or if symptoms last longer than would be expected for tissue healing<sup>23</sup>. NP is debilitating and can have a negative impact on a person's quality of life (QoL), affecting their psychological, social and physical functioning<sup>31</sup>. There are various treatments available including anticonvulsants, antidepressants, opioids, regional analgesics, surgical procedures, and psychological therapies<sup>27</sup>. For more intractable conditions, individuals are offered Spinal Cord Stimulation (SCS) surgery.

SCS is a surgically implanted device that delivers electricity to the spinal cord, changing the pain messages sent to the brain<sup>43</sup>. Prior to full implantation, patients undergo trial stimulation to determine whether effective pain relief of at least 50% is achieved<sup>9</sup>. Recent randomised controlled trials (RCTs) indicate SCS is effective in reducing pain and medication use, improving QoL, functional capacity, and patient satisfaction in carefully selected patients<sup>18,20</sup>. There is also evidence of a reduction in emotional distress following SCS implantation<sup>17</sup>. Although, SCS is beneficial to certain NP conditions<sup>31</sup>, there is a substantial subset of patients who do not benefit<sup>10</sup> or who experience loss of efficacy over time<sup>4,30</sup>.

Literature suggests psychological factors may partially explain these differences<sup>3</sup>, with reviews indicating that psychological factors (e.g. depression, anxiety, somatisation and poor coping) can predict SCS outcomes<sup>5</sup>. The European Federation of the International Study of Pain Chapter's (EFIC) guidelines recommend that psychological evaluation is undertaken as part of the SCS screening process to rule out contraindications, such as an unresolved major psychiatric disorder (e.g. psychosis, severe depression), substance misuse, or

lack of social support<sup>12</sup>. However, currently there are no 'gold standard' measures proposed for such assessment<sup>42</sup>. Also, as psychological evaluation was originally largely driven by medical insurance requirements in the United States (US), it is still not consistently applied within the UK<sup>1</sup>.

The SCS literature provides valuable knowledge on patient suitability, SCS technology and treatment effectiveness using a range of outcome measures. However, there is a dearth of in-depth qualitative analysis of what it means to have SCS surgery from a patient perspective. Exploratory qualitative research has provided psychological insights into the experience of chronic pain and other surgical procedures<sup>7,39</sup>. The qualitative literature on chronic pain describes a discrepancy between patients' painful bodies and their preferred selves as a barrier to therapeutic rehabilitation; specifically, it impedes progress towards acceptance of this changed identity<sup>39</sup>. Additionally, qualitative studies have provided insights into NP patients' experiences of accessing pain relief treatments, although not SCS. Research indicated that patients felt insignificant, poorly understood and dismissed, whilst being referred from service to service<sup>46</sup>. Therefore, patients not only felt let down by their bodies<sup>40</sup> but also by services, leaving them feeling "trapped"<sup>46</sup>. Researching the experience of the SCS journey therefore could be particularly important in understanding how patients came to have SCS, their experience of the surgery, and the outcome.

Previous qualitative literature on the experience of patients who have had surgically implanted devices has offered valuable insights into patient experiences of Implantable Cardioverter Defibrillator (ICD) and how they adjust physically and psychologically<sup>7</sup>. Although the purpose of the device is different to SCS, such research demonstrates the depth of information gained about adapting to this device. Prior to implant, patients in the study had experienced

misdiagnosis, hopelessness, loss of functioning and felt dismissed by healthcare professionals. This is consistent with the chronic pain literature. Post-implantation patients gained control of their symptoms and felt independent as they no longer had to heavily rely on healthcare professionals. Furthermore, despite experiencing anxiety associated with the internal shocks, externally they felt that some normality had been restored. The specific qualitative analysis employed for this study was unclear. However, it allowed a richer, more detailed exploration of patients' experience of the ICD pre- and post-surgery. Such insights on SCS could provide important information currently missing in the SCS literature.

In summary, there is a lack of in-depth analysis of the lived experience of the SCS surgery treatment journey. This research is the first qualitative study to systematically analyse SCS patient experiences from a phenomenological perspective. Using Interpretative Phenomenological Analysis (IPA)<sup>35</sup>, the aim of the current research was to gain a patient perspective of the lived experience of the SCS treatment journey, providing further insights for SCS teams and prospective patients; specifically, how patients make sense of their life of chronic NP prior to, and after implantation of the stimulator .

## **Method**

### *Design*

As informed by the literature review and research objective, the researchers employed a retrospective qualitative design. IPA<sup>35</sup> was used to explore the participants' experiences of their treatment journey of SCS surgery. To achieve this, the first author (AT) attempted to understand how participants made sense of their experience<sup>33</sup>. In contrast to quantitative research which uses representative groups or populations to make probabilistic claims and generalisations, IPA studies take an idiographic approach<sup>34</sup>, which

entails completing a detailed, nuanced analysis of the experience of a small sample of participants<sup>38</sup>.

### *Participants*

Seven participants were purposively selected from a neurosurgery department. The participants were homogeneous in that they had all undergone SCS surgery to treat chronic NP; however, the specific origin of their pain and other demographic information varied. The sample consisted of four females and three males, aged 43-68 years. All participants were identified as White British, and had experienced back and/or leg pain for 6-21 years. All had chosen to have SCS surgery following the failure of alternative pain treatments to provide adequate pain relief and/or due to negative medication side-effects. Two participants had previously undergone SCS surgery, but due to complications the SCS had to be removed and replaced. All identifying information has been changed to protect participants' anonymity.

### *Procedure*

Following approval from the Regional Ethics Committee and the R&D department, the neurosurgery department sent information packs to all patients meeting the inclusion criteria. Participants had to have undergone SCS surgery within the past 2-8 months, were aged 18 or over, spoke English, and consented to take part. The time scale allowed for a period of post-surgery recovery, but interviews were undertaken soon enough after the surgery for participants to recall life leading up to and after the surgery. AT obtained written consent alongside demographic information, and interviewed the participants in their homes. All interviews were audio recorded and lasted between 43 - 96 minutes. Following the interview, participants were debriefed and offered information on support services available. Initial reflections on the interview content were recorded and notes were made in a research journal.

In accordance with IPA methodology, a semi-structured interview schedule was developed to guide the interview (see Table 2). This provided flexibility through the use of prompts allowing exploration of interesting claims or concerns that arose. The schedule followed a chronological sequence to capture experiences before and after SCS. As SCS is only considered after standard treatments have failed<sup>27</sup>, it was important to include life prior to pain and previous pain treatments to understand what life had been like for patients to bring them to consider SCS.

TABLE 2

*Interview Schedule*

Interview Questions
1. To begin with, describe what life was like before your surgery?
2. Prior to the surgery, did experiencing pain change the way you thought or felt about yourself?
3. How did you feel when the surgery was suggested to you?
4. How would you describe living with the device implanted in you?
5. Having had the surgery, describe how life has been?
6. Having had the surgery, how would you describe yourself now?
7. Having had the surgery, how do you see yourself in the future?
8. Additional prompts: Can you tell me more about that? What sense did you make of that?



### *Data analysis*

AT transcribed the audio recordings verbatim to provide the raw data for analysis. IPA does not provide a single method to analyse data, but offers flexible guidelines which can be modified to meet the research objectives<sup>34</sup>. This study drew on the most recent guidelines by Smith and colleagues<sup>33</sup>, which involved employing specific techniques to identify patterns in the data at different stages of the analysis. The first transcript was read and re-read and initial exploratory coding including descriptive, linguistic and conceptual comments were noted. Initial themes were generated to reflect a summarised understanding of the exploratory coding. The initial themes were then listed and similar themes were collapsed together. From this data, super-ordinate and sub-ordinate themes were generated. The same procedure was adopted for subsequent transcripts, completing an individual case-by-case analysis<sup>34</sup>. Patterns across the cases were then examined and themes were organised and combined.

### *Quality assurance*

To ensure research credibility and quality assurance, Yardley's guidelines were adhered to<sup>8,48</sup>. AT sought a critical voice from a member of the research team (RdN) to enhance the credibility of the interpretative process. Gaining convergence of ideas was not the focus, as accuracy and objectivity are not in line with the critical realist epistemological position the authors took, pertaining to multiple perspectives on reality. However, the aim was to ensure that all interpretation was clearly embedded in the data which can also be seen explicitly by the use of direct quotes presented. Trustworthiness was achieved through using a reflective diary to document all decision making, creating an audit trail from interviews to write-up. This provided transparency and a coherent narrative throughout the research process contributing to the rigour of the findings<sup>8</sup>. It also

allowed for recognition of prior knowledge and ideas that might influence the process.

## **Results**

Three interrelated super-ordinate themes were generated from the analysis: diminished control and coping, identity transitions, and SCS conflict, each of which contained sub-themes (see Table 3). The themes included either information from before or after the SCS surgery, or information from both. This was contextualised by participants' quotes. It is recommended that three quotes be presented for each theme<sup>36</sup>. However, in order to present a snapshot of the treatment journey, only one or two quotes are presented to exemplify a sub-theme.

TABLE 3

*IPA Analysis: Super-ordinate and Sub-themes*

Super-ordinate Theme	Sub-themes
Diminished control and coping	Battling the system and managing expectations  Multiple levels of powerlessness  Coping with symptoms of depression  Impact of pain and the non-able body
Identity transitions	Identity loss  Managing the unwanted pain identity
SCS conflict	Positive change  Disappointment, adaptation and acceptance

*Diminished control and coping*

This super-ordinate theme encapsulates the diminished sense of control experienced by participants both prior to and after SCS surgery as they attempted to cope with the impact of their chronic NP. Four sub-themes were identified.

### *Battling the system and managing expectations*

This reflects participants' arduous journey through various treatments and associated hopes and disappointments. All participants were persistent in attending pain clinics, despite numerous treatment failures including previous surgical procedures. Devastation at the lack of progress permeated these stories, often leaving participants feeling desperate by the time they were offered SCS. Nicole poignantly reflects this when she described attending the panel that assessed her suitability for SCS:

*Nicole: 'I got called up to the panel (pause), which is where I learnt a little bit more about it [SCS], but at that point I'd had tried anything...Because I was at the point...I was ready to drive into a brick wall I had had enough, errr, er, pain levels were, there was no sort of respite, at all'*

Due to such desperation, managing expectations of treatments was a key part of this journey. All participants described faith in SCS; for two participants their hopes were increased by the SCS trial, but for the others it seemed to be a faith based on a persistent hope for something better. Specific expectations of SCS differed amongst participants. Some participants reported maintaining low expectations of SCS due to previous treatment disappointments and explanations about what to expect, whereas others had higher expectations:

*Maya: 'they did sort of say, y-you know, it may work for you, it may not work for ya...you do go into it thinking, you know I'll be able to do this, that and the other [after SCS]...you have to accept you can't do that, erm, but the expectations, I wanted more'.*

Such expectations were linked to participants' subsequent satisfaction with their SCS as illustrated in the theme SCS conflict.

This faith in SCS motivated two participants to persist in their fight to get a stimulator despite numerous barriers related to funding. This resulted in anger and upset as they tried to gain some control of this pursuit. Sally progressed from bargaining '*let me have it done, and I'll walk away*' to pleading '*let me have this one chance*' to pestering '*I kept pestering*' in desperation for her SCS, perceiving this as her '*final chance of getting some pain relief*'. Yet simultaneously, she tried to retain an open-mind about the outcome as her previous SCS malfunctioned. Within this was a sense of powerlessness as captured in the next theme.

### *Multiple levels of powerlessness*

Multiple levels of powerlessness were interwoven throughout six participants' experiences, overlapping with all other themes. All participants alluded to a sense of powerlessness to their pain due to it dictating what they could and could not do. This powerlessness was also experienced in relation to the side-effects of the medication, negative hospital experiences, in relation to fighting for a stimulator, adapting to it, or simply fate. This powerlessness to the system was present in the majority of Sally's and Sarah's account. Sally's initial loss of control was when her first SCS had to be removed. However, she was then denied a replacement due to her not getting the required 50% pain relief. As she expressed her anger at her subjective experience not being valued, she likened SCS to a commodity to be traded to convey her sense of injustice.

*Sally: 'I'm kind of piggy in the middle, it's my body your cutting open, stuffing an implant in, surely if I'm happy with 10, 15 percent then it should be done, if you brought a product from anywhere and it was faulty, you would take it back, you would either get your money back or you'd get another one'*

Sally was unable to comprehend this disparity in opinions about what constituted 'adequate pain relief' leaving her feeling devoid of agency. In contrast, Jack and Pete alluded to a higher sense of powerlessness that nobody could control.

*Pete: 'Describe myself now (pause)...Um (pause), cheated...Not by the NHS but by some, you know, some act of God, or some fate that suddenly changes your life from this (points to legs) to this (points to stimulator) in one phuff (noise with mouth).'*

This external locus of control exhibited by participants had a negative impact on thought processes and mood. Participants described a 'no win situation' (Jack), with little control over their lives, contributing further to their desperation for some positive change.

#### *Coping with symptoms of depression*

All but one participant described an ongoing struggle with experiencing and coping with depressive symptoms prior to SCS. One participant reported these ceased following surgery, however for the others they persisted. There was variation in participants' specific symptoms (e.g. low mood, ruminative thinking and loss of motivation), and their coping strategies. However, all six participants experienced feelings of hopelessness at some point in their journey. Jack coped by challenging his negative thinking, whereas Mike and Pete talked about ensuring they had a purpose in their day to break the cycle of feeling low.

*Pete: 'you've gotta have a reason to get up in the morning...otherwise, you'll just drift into this, this state of...'I'll not have a shave today, I'll not have a wash today, cos I'm not going anywhere'.*

Participants' symptoms were exacerbated by challenging situations like Sarah's difficulties in obtaining her stimulator. In her desperation for pain relief, she feared being denied SCS for exhibiting low mood and distress, so began concealing her emotions from healthcare professionals. She described feeling emotionally unsupported during this process, leaving her feeling angry:

*Sarah: 'I should have been able to be emotional, I should have been able to talk to someone that helped me be ok for the spinal cord stimulator, and help me be ok if it didn't work'.*

The lack of emotional support at different points in the SCS treatment journey was echoed by other participants, particularly post-operation during the adaptation process. Pete reported the benefits of being able to talk about his SCS experience in the interview: *'it's been nice to get it out, and in fact I might feel a lot different [about his SCS] now, I've actually sat down and phuff (noise with mouth) and brought it out'*. This quote highlights the positive release Pete achieved and the potential it had to change to his perceptions.

#### *Impact of pain and the non-able body*

All participants described activity limitations, participation restrictions, multiple losses and dependence as a result of their pain. Social losses were most prevalent due to the physical restrictions as illustrated by Nicole:

*Nicole: 'I don't have a social life anymore... if you can't keep up with the people, ermm, they just don't want to know (pause), erm, after a while, er everything you do, ends up, to able-bodied people in a way, as a hindrance'.*

Nicole felt like a burden to others; a sentiment also expressed by Sarah, who coped by withdrawing from social situations:

*Sarah: 'The reason I'd be saying no [to social event], maybe wasn't so much about the pain, as to (pause) why would they want me there, cos I'm just a burden (pause, tears rolling down face) so I'd say no cos of that'.*

The feeling of being a burden reduced Sarah's sense of self and desire to interact socially. The burden of the non-able body was peppered through accounts alongside the inherent powerlessness that accompanies it. Participants' bodies prevented them from fully engaging in the world, a rupture resulting in social exclusion, reduced mood, and low self-esteem. Understanding this restrictive pain reality helps to contextualise participants' desire for SCS. However, in this group of participants the level of change from SCS on these aspects of their lives varied as is discussed in the 'SCS conflict' theme.

#### *Identity transition*

This theme represents identity loss and changes in participants' sense of self as a result of their pain. This consisted of two sub-themes:

##### *Identity loss*

All participants described loss of identities. The loss of the pre-pain, active self was predominant in all accounts, which often resulted in loss of social contacts and associated social identities:

*Mike: 'I was fairly active, well very active, I use to like easy sports, tennis and stuff like that...and then things slowed down...cos of the pain, I couldn't do as much'*

*Pete: 'I use to be part of a walking club, we used to do hill walking, I don't see any of them anymore, because I don't go walking'.*



There was a sense of mourning these lost selves, with participants making comparisons to who they were and who they had become, consequently leaving a void in their sense of who they are. For most participants, the gains from SCS left them with a sense of needing to accept their losses, what had and had not changed, and adapt to this unwanted pain identity.

### *Managing the unwanted pain identity*

The 'pain identity' included both personal characteristics of what participants are like when in pain and how they manage pain socially. Every account included reflections of managing an unwanted pain identity, both prior to, and after SCS surgery. Pain persistence and severity underpinned all accounts which contributed to an understanding of this as a stable identity like gender, ethnicity or race, as depicted by Sally *'It [pain] were just, just part of me I suppose'*. The way the pain identity manifested differed across participants but broadly fell into two categories: Anger (demanding, aggressive)/shame or quiet and withdrawn. For Pete, his *'personality change'* was too painful to accept. This is reflected in the content of his account and his inconsistent use of pronouns which may provide distance for him from this undesirable aspect of himself:

*Pete: 'I get aggressive a lot...it isn't me, this person from the last 10 years isn't me....you don't want to be like that, you don't want to, you don't want to treat other people like because you know they're are trying to help you but you just want to be left alone, you just want to be (hesitates), packed away into your own life'.*

This sense of shame of his pain identity was echoed in other accounts in relation to emotional expression. Participants masked their pain identity by suppressing emotions or concealing their experience of pain from others, often due to the fear of social consequences of revealing this. It seemed the process of accepting

this part of their identity prevented talk of future identities for most participants.

### *SCS conflict*

This theme represents what the SCS outcome meant to participants. All participants, apart from Sally, experienced conflicting feelings about their stimulator. Five participants weighed up the positive and negative aspects of SCS. In contrast, Pete felt grateful for it, but felt his life was no different. These are documented as two sub-themes:

### *Positive change*

‘Positive change’ encompasses the multiple ways in which SCS positively influenced participants on an individual and interpersonal level. All participants, apart from Pete, reported that the reduction in pain made them happier and provided some with optimism for the future. Such change was pivotal for some who had previously felt hopeless about their future. This is reflected in Nicole’s statement summarising how SCS broke her cycle of hopelessness:

*Nicole: ‘It’s [SCS] probably the best thing that’s happened in the last eight years...I suppose in the long run, it’s probably saved my life...it’s given me the chance to start looking forward’.*

Participants described small but significant changes to activities of daily living. Being able to sit or stand for longer periods helped them at work, in home life, or socially. However, one of the most prevalent positive outcomes for participants was looking forward to reducing their medication use, and ultimately the negative side-effects. SCS instilled a sense of control for Sally, Maya and Jack; which for Jack was a contrast to the perceived loss of control he experienced after taking medication:

*Jack: 'I think I'd rather use the stimulator [not medication] because even though it's taking, it's only taking part of it [pain] off, I feel like I am in control of that'.*

These changes were weighed up with other less desirable aspects of the SCS, leaving most participants feeling ambivalent, or as Sarah described, feeling *'in limbo'*.

### *Disappointment, adaptation and acceptance*

All participants apart from Sally conveyed disappointment with certain aspects of their SCS, predominantly related to adapting to its presence and using the stimulator. This was coupled with a process of acceptance of their current pain relief and capabilities. All six participants alluded to adapting to the attention required by the stimulator, due to the visibility or discomfort of the battery, side-effects, or as a result of having to frequently change the settings on the device depending on what they were doing. Four participants described experiencing unpredictable side-effects (e.g. shocks, loss of leg control, or feeling off-balance) which added to the powerlessness they already experienced. This contrasted to the sense of control some participants experienced following the implant. Jack felt particularly paranoid about the shocks and anxious about when they would happen:

*Jack: 'you get the shocks depending on what you're doing, so I do get a little paranoid as to what I'm doing and sometimes I just think I'm turning it off, cos I, having a break from it almost, you know, yet I do think it has been a god sent'.*

This example illustrates not only the adaptation to SCS, but also his SCS conflict. Jack alluded to not only using SCS for pain respite, but also needing a break from his SCS, yet he still was keen to express how positive he feels about it. There is a sense that despite these

effects, he still has choice and control over whether to have the SCS switched on, unlike the medication, which once taken, it is out of his control.

Participants' expectations of SCS were closely linked to subsequent disappointment. Although, three of these six participants reported an increase in mobility/functioning, the others experienced no improvement in their functioning, or less than they expected. Therefore the rupture between their bodies and the world continued to exist. For Sarah, her freedom from pain and improved mood failed to free her from her non-able body and its implications:

*Sarah: 'I can't do much more...so financially I'm screwed anyway, I can't go out, so still stuck in 'ere, although I'm not in as much pain, I mean the walls start crawling in on you regardless. You could be the happiest person in the world, but eventually you'd go stir crazy'.*

Therefore, participants were experiencing a process of acceptance of their level of pain relief and capabilities. This process could be the start of the end of their battle. Having tried most, if not all treatment options, it represented an opportunity to stop trying and accept life as it is. However, the gravity of this task in reality was a daunting prospect *'I feel like I'm just, I-I feel like this is rest of me life to be honest'* (Jack).

## **Discussion**

The current research aimed to explore seven individuals' experience of the SCS treatment journey considering life prior to and after SCS surgery. The data analysis revealed three super-ordinate themes: diminished control and coping, identity transitions and SCS conflict. These themes link to existing literature on SCS surgery preparation and outcome, as well as the constructs described in the chronic pain literature (e.g. identity) and the impact of pain.

The current study highlights how the experience of SCS cannot be considered in isolation from coping with the journey that precedes it. Participants persisted with experimenting with various treatments and experiencing associated hope and disappointment. This was consistent with existing research<sup>6</sup>, suggesting chronic NP patients cope with their pain through proactive attempts to seek help, and despite disappointment they show a willingness to try any possibility<sup>6</sup>. This has been suggested to be a means to gain control<sup>21</sup> due to the sense of powerlessness and consequent desperation evoked by the pain experience<sup>3</sup>. However, this desperation for a 'cure' could have implications for the success of SCS surgery, or *perceptions* of success<sup>42</sup>. Certainly, participants discussed expectations and faith in SCS which appeared to impact on their satisfaction with the clinical outcomes. Research indicates the extent to which pre-operative expectations are fulfilled, influences post-operative satisfaction in lumbar and cervical spine patients<sup>41</sup>. Furthermore, Kumar and colleagues<sup>20</sup> in their PROCESS study reported that only 55% of the patients using the SCS found it (50% or above) beneficial at 6 months and 40% at 24months. This significant drop in reported efficacy could be caused by mismanagement of expectations which is consistent with the current findings. This reinforces recommendations to address patient beliefs and expectations prior to SCS surgery<sup>3,9</sup>. In addition to this, for two participants this process was further complicated by difficulties in accessing SCS. There is a dearth of literature on patients' experiences of attaining SCS. Initial insights from the current study suggest emotional support may be helpful during this process when complications arise, as the consequent powerlessness and associated anxiety could further exacerbate patients' pain experience<sup>45</sup>.

The physical restrictions and activity limitations associated with participants' pain resulted in loss of roles and social identities, as well as the presence of depressive symptoms. This is consistent with the

chronic pain literature<sup>14,25-26</sup>. All but one of the participants reported feeling more positive, whether due to a reduction in their pain and/or improvements in activities of daily living (e.g. sitting/standing longer). This is consistent with research indicating SCS can reduce emotional distress<sup>17</sup>, improve pain-associated depression<sup>28</sup>, and QoL<sup>19</sup>. It seemed the positive effects of the stimulator disrupted feelings of persistent low mood, lack of successful pain relief and hopelessness. However, when discussing the broader context of their lives post-surgery, participants continued to allude to coping with depressive symptoms. Although pain relief was the primary goal, the findings suggest SCS also represented hope to make changes to social circumstances through increasing functioning. This is supported by research investigating patients' hopes of improvement in relation to QoL prior to SCS which suggested functional status was the most important benefit patients hoped to gain from SCS<sup>2</sup>. The diversity of outcomes to SCS in the current study meant certain expectations were met, and some were not. This left most participants unable to reclaim pre-pain identities or losses, and instead they were going through a process of acceptance. Illness can threaten identity: first there is the loss; then comes the redefining and rediscovering of identities<sup>16</sup>. Given that most participants saw SCS as their last option, they appeared to be experiencing this process of acceptance with less reference to re-discovering roles at this point. Being able to accept identity loss and their pain identity is important as not doing so may impede rehabilitation<sup>39</sup>.

Furthermore, being able to accept pain levels and give up unproductive attempts to control pain can lower pain intensity, decrease depression and physical and psychosocial disability<sup>21-22</sup>. Therefore, some SCS patients may benefit from additional physiological and psychological interventions to improve functioning<sup>26,44</sup> and to assist with associated emotions and behaviours during this acceptance process. A suggested treatment

for chronic pain is Acceptance and Commitment Therapy (ACT) which aims to increase functioning and reduce interference of pain by changing individuals' relationship with pain, by focusing on achieving value-driven goals and acceptance as oppose to trying to control pain<sup>15</sup>. A recent RCT (n=114) comparing ACT and Cognitive Behavioural Therapy (CBT) in treating chronic pain indicated ACT participants showed improvements on pain interference, depression, pain-related anxiety, and reported higher levels of treatment satisfaction than the CBT group<sup>47</sup>. Such a treatment could be used adjunctively to SCS, alongside behavioural treatments encouraging patients to incrementally increase activity levels with their new level of pain relief gained from the stimulator<sup>44</sup>.

The current study highlighted that participants were simultaneously adapting to living with their SCS and the associated side-effects during this acceptance process. The occurrence of side-effects is clearly documented in literature<sup>28</sup>. However, there is a paucity of literature about patients' perspective about the side-effects, or how to assist patients to adapt and cope with their new devices, medication reduction and associated anxieties. The unpredictable nature of the side-effects further induced a sense of powerlessness and left participants with conflicting feelings about their positive gains and more negative aspects of the device. Wider literature on ICDs discussed patients' adaptation to the psychological and physical impact of the device and the shocks delivered to regulate their heart beat<sup>7,11,13</sup>. Whilst the function of an ICD is very different to SCS, the experience of adapting to an internal device, and the associated shocks, is comparable to participants' narratives in the current study. The significance here is the reported feelings of loss of control have been associated with helplessness and high levels of depression<sup>11</sup>. This is important when considering patients' adjustment to the stimulator and further research into factors facilitating and impeding control of, and adjustment to SCS is required.

### *Clinical implications*

The findings from this analysis contribute to existing literature by providing an in-depth understanding of the experience of the SCS treatment journey. This included coping with pre-surgery expectations, the process of accepting SCS outcomes and subsequent losses alongside the challenges of adapting to the stimulator.

Some literature recommends pre-surgery preparations for SCS implantation including psychological assessment, psycho-education and supporting patients with beliefs and expectations about the surgery<sup>44</sup>. In light of patient willingness to try any treatment, attention should be given to patients' ability to take in significant information during the SCS assessment. Information should be provided in a number of formats, and adequate time should be spent exploring the meaning of patients' pain experience, and gaining specific details about expectations and goals in order to address any overly optimistic expectations<sup>3,9,44</sup>. Furthermore, it has previously been suggested that providing potential SCS patients with the opportunity to talk to patients already implanted may help prepare patients for the surgery and post-surgery adjustment<sup>44</sup>. One study suggested patients with health difficulties find 'counsellors' with similar problems more credible information providers than healthy trained professionals<sup>29</sup>.

The literature recommends postsurgical psychological support and monitoring<sup>44</sup>. Postsurgical support in the UK often includes meetings with the surgeon and nursing staff to adjust the stimulator settings; however, it remains unclear how frequently psychological support is provided during the SCS adaptation process. The current findings suggest multidisciplinary support including psychological input should be offered to patients adapting to the presence, or use of their SCS. This can allow evaluation of whether patients' expectations have



been met, their current levels of mood and functioning, and may also assist with the psychological effects of reduced opioid medication usage. For relevant patients, SCS could be combined with physiotherapy and psychological therapies (e.g. ACT) to restore functional capacity, to work through losses and facilitate pain acceptance, providing more holistic postsurgical pain management. This could assist in reducing feelings of powerlessness by helping patients feel less isolated and more emotionally contained.

### *Limitations*

A limitation of the study is the retrospective nature of the accounts, as the detail of events may be subject to memory recall and it assumes participants have the ability to articulate relevant information<sup>37</sup>. However, non-verbal cues, metaphors and emotions during the interview provided other forms of communication of participants' experiences. Also, the purpose of the study was to capture the participants' meaning-making in the here-and-now, with the understanding that their perception of events may alter if conducted in a different time or place. The findings are specific to this group of individuals and the study did not intend to make generalisations about the results to all SCS patients as this is not in line with the idiographic approach of IPA<sup>33</sup>. Instead, the finding of the study can inform current practice in neurosurgery departments and pain management multidisciplinary teams working with SCS patients experiencing similar challenges.

### *Future research*

Future research could undertake longitudinal qualitative research, collecting data throughout the treatment journey (i.e. prior to surgery, a month post-surgery and then a follow up at six month, then a year). This would provide more in-depth information about surgery expectations, outcomes, and coping processes relating to accepting any lack of change and adapting to the living with the stimulator. It

also may provide further insights into the loss of analgesia reported over time<sup>4,30</sup>. More qualitative research on specific parts of the SCS treatment journey could provide further insights into the assessment process and coping with adjusting to the SCS.

Furthermore, a future RCT could compare a treatment group with SCS and conventional medical treatments (CMT; medication) with consistent psychological support during assessment and post-surgery interventions, to another group with SCS and CMT only. This could help determine if SCS was more effective with additional psychological support.

### **Conclusion**

The current research supports previous research in the importance of identifying and addressing expectations of SCS during pre-surgical preparations. High expectations may reduce patient satisfaction with the outcomes of the stimulator. Additionally, if there are complications in accessing a stimulator, emotional support may be beneficial to prevent patients feeling powerless and anxious, which can exacerbate the pain experience. Lastly, in line with previous research, the current research indicates that psychological interventions may be useful for some patients as an adjuvant to SCS post-surgery. Patients may experience a process of acceptance of current pain levels and capabilities as well as having to simultaneously adjust to living with the stimulator on a psychological and practical level. Psychological support could, when appropriate, focus on mitigating remaining interference in functioning, assisting with identity transitions and pain acceptance, and to aid adjustment to the internal presence of the stimulator and living with the device.

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## References

1. Ackroyd R, Bush DJ, Graves J, McVey J, Horton S: Survey of assessment criteria prior to implantation of spinal cord stimulators in United Kingdom pain management centres. **European Journal of Pain** 9:57-60, 2005
2. Anderson VC, Carlson C, Shatin D: Outcomes of spinal cord stimulation: patient validation. **Neuromodulation: Technology at the Neural Interface** 4:11-17, 2001
3. Beltrutti D, Lamberto A, Barolat G, Bruehl S, Doleys D, Krames E, et al: The psychological assessment of candidates for spinal cord stimulation for chronic pain management. **Pain Practice** 4:204-221, 2004
4. Cameron T: Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. **Journal of Neurosurgery: Spine** 100:254-267, 2004
5. Celestin J, Edwards RR, Jamison RN: Pretreatment psychosocial variables as predictors of outcomes following lumbar surgery and spinal cord stimulation: a systematic review and literature synthesis. **Pain Medicine** 10:639-653, 2009
6. Closs SJ, Staples V, Reid I, Bennett MI, Briggs M: Managing the symptoms of neuropathic pain: An exploration of patients' experiences. **Journal of pain and symptom management** 34:422-433, 2007
7. Deaton C, Dunbar SB, Moloney M, Sears SF, Ujhelyi MR: Patient experiences with atrial fibrillation and treatment with implantable atrial defibrillation therapy. **Heart & Lung** 32:291-299, 2003
8. Denzin NK, Lincoln YS: **The Sage handbook of qualitative research**: Sage Publications, Inc, 2011
9. Doleys DM: Psychological factors in spinal cord stimulation therapy: brief review and discussion. **Neurosurg Focus** 21:E1, 2006
10. Giordano N, Lofland K: A literature review of psychological predictors of spinal cord stimulator outcomes. **The Journal of Pain** 6:S67-S67, 2005
11. Goodman M, Hess B: Could implantable cardioverter defibrillators provide a human model supporting the learned helplessness theory of depression? **General hospital psychiatry** 21:382-385, 1999
12. Gybels J, Erdine S, Maeyaert J, Meyerson B, Winkelmüller W, Augustinsson L, et al: Neuromodulation of pain. A consensus statement prepared in Brussels 16-18 January 1998 by the following task force of the European Federation of IASP Chapters (EFIC). **European journal of pain (London, England)** 2:203, 1998
13. Hallas CN, Burke JL, White DG, Connelly DT: Pre ICD Illness Beliefs Affect Postimplant Perceptions of Control and Patient

- Quality of Life. **Pacing and Clinical Electrophysiology** **33**:256-265, 2010
14. Harris S, Morley S, Barton SB: Role loss and emotional adjustment in chronic pain. **Pain** **105**:363-370, 2003
  15. Hayes SC, Duckworth MP: Acceptance and commitment therapy and traditional cognitive behavior therapy approaches to pain. **Cognitive and Behavioral Practice** **13**:185-187, 2006
  16. Henare D: It just isn't me anymore" moving forward to a new identity. **New-Zealand Journal of Occupational Therapy** **50**:4-10, 2003
  17. Jamison RN, Washington TA, Fanciullo GJ, Ross EL, McHugo GJ, Baird JC: Do Implantable Devices Improve Mood? Comparisons of Chronic Pain Patients With or Without an Implantable Device. **Neuromodulation: Technology at the Neural Interface** **11**:260-266, 2008
  18. Kumar K, Rizvi S, Bnurs SB: Spinal Cord Stimulation Is Effective in Management of Complex Regional Pain Syndrome I: Fact or Fiction. **Neurosurgery** **69**:566-578, 2011
  19. Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, et al: Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomised controlled trial in patients with failed back surgery syndrome. **Pain** **132**:179-188, 2007
  20. Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, et al: The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. **Neurosurgery** **63**:762-768, 2008
  21. McCracken LM: Learning to live with the pain: acceptance of pain predicts adjustment in persons with chronic pain. **Pain** **74**:21-27, 1998
  22. McCracken LM, Eccleston C: Coping or acceptance: what to do about chronic pain? **Pain** **105**:197-204, 2003
  23. Medical Advisory Secretariat: Spinal cord stimulation for neuropathic pain: an evidencebased analysis. **Ontario Health Technology Assessment Series** **5**:1-78, 2005
  24. Merskey H, Bogduk N: Classification of chronic pain: descriptions of chronic pain syndromes and definitions of pain terms. 1994
  25. Miles A, Curran H, Pearce S, Allan L: Managing constraint: the experience of people with chronic pain. **Social science & medicine** **61**:431-441, 2005
  26. Morley S: Psychology of pain. **British journal of anaesthesia** **101**:25, 2008
  27. National Institute of Health and Clinical Excellence: Spinal Cord Stimulation for chronic pain of neuropathic or ischaemic origin, in **NICE technology appraisal guidance** **159**: NHS, 2008, pp 1-36

28. North R, Shipley J: Practice parameters for the use of spinal cord stimulation in the treatment of chronic neuropathic pain. **Pain Medicine** 8:S200-S275, 2007
29. Nosek MA, Fuhrer MJ, Hughes SO: Perceived counselor credibility by persons with physical-disability - influence of counselor disability status, professional status, and the counseling content. **Rehabilitation Psychology** 36:153-161, 1991
30. Ohnmeiss DD, Rashbaum RF: Patient satisfaction with spinal cord stimulation for predominant complaints of chronic, intractable low back pain\* 1,\* 2,\* 3. **The Spine Journal** 1:358-363, 2001
31. Simpson EL, Duenas A, Holmes MW, Papaioannou D, Chilcott J: Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. **Health Technol Assess** 13:iii, ix-x, 1-154, 2009
32. Smith H, Joint C, Schlugman D, Nandi D, Stein JF, Aziz TZ: Motor cortex stimulation for neuropathic pain. **Neurosurgical Focus** 11:1-9, 2001
33. Smith J, Flowers P, Larkin M: **Interpretative phenomenological analysis: theory, method and research**: Sage Publications Ltd, 2009
34. Smith J, Osborn M: About IPA. **Qualitative psychology: A practical guide to research methods**. London: Sage, 2008
35. Smith JA: Beyond the divide between cognition and discourse: Using interpretative phenomenological analysis in health psychology. **Psychology & Health**, 1996
36. Smith JA: Evaluating the contribution of interpretative phenomenological analysis. **Health Psychology Review** 5:9-27, 2011
37. Smith JA: Qualitative methodology: analysing participants' perspectives. **Current Opinion in Psychiatry** 9:417, 1996
38. Smith JA: Reflecting on the development of interpretative phenomenological analysis and its contribution to qualitative research in psychology. **Qualitative Research in Psychology** 1:39-54, 2004
39. Smith JA, Osborn M: Pain as an assault on the self: An interpretative phenomenological analysis of the psychological impact of chronic benign low back pain. **Psychology and health** 22:517-534, 2007
40. Snelgrove S, Liossi C: An interpretative phenomenological analysis of living with chronic low back pain. **British journal of health psychology** 14:735-749, 2009
41. Soroceanu A, Ching A, Abdu W, McGuire K: Relationship Between Pre-Operative Expectations, Satisfaction and Functional Outcomes in Lumbar and Cervical Spine Patients: a Multi Center Study. **Spine**, 2011
42. Sparkes E, Raphael JH, Duarte RV, LeMarchand K, Jackson C, Ashford RL: A systematic literature review of psychological

- characteristics as determinants of outcome for spinal cord stimulation therapy. **Pain 150**:284-289, 2010
43. The British Pain Society: Spinal cord stimulation for pain: Information for patients. The British Pain Society: 1-12, 2005
  44. Van Dorsten B: Psychological considerations in preparing patients for implantation procedures. **Pain Medicine 7**:S47-S57, 2006
  45. Walding MF: Pain, anxiety and powerlessness. **Journal of Advanced Nursing 16**:388-397, 1991
  46. Walker J, Holloway I, Sofaer B: In the system: the lived experience of chronic back pain from the perspectives of those seeking help from pain clinics. **Pain 80**:621-628, 1999
  47. Wetherell JL, Afari N, Rutledge T, Sorrell JT, Stoddard JA, Petkus AJ, et al: A randomized, controlled trial of acceptance and commitment therapy and cognitive-behavioral therapy for chronic pain. **Pain 152**:2098-2107, 2011
  48. Yardley L: Dilemmas in qualitative health research. **Psychology Health 15**:215-228, 2000

## **EXTENDED PAPER**



## **1.0 Extended Paper**

I have written the extended paper to be read in conjunction with the journal paper. This will provide additional information on the background of the research and rationale for the study. It will also provide further details about the methodology, analysis and an expansion on the discussion. Lastly, I will present a critical reflection of the research process, the decision making and conclusions drawn.

### **1.1 Rationale for journal choice**

I have written my journal paper to be submitted to the *Journal of Neurosurgery*<sup>4</sup>. This journal has previously published qualitative studies and articles on spinal cord stimulation (SCS). I felt that submission to this journal would reach the intended audience, as I hoped my research would provide insights to the pain management multidisciplinary teams working with SCS patients. This often includes neurosurgeons, nurses, clinical psychologists, physiotherapists and representatives of the stimulator manufacturers. However, I felt this was particularly important for the neurosurgeons for two main reasons. Firstly, I aimed to add to their understanding of what it means to the patients to go through the SCS treatment journey. Secondly, with SCS, the relationship between the surgeon and patient involves frequent and long lasting contact (Gybels et al., 1998). The patients often require battery changes for their stimulator every few years and the surgeons will also assist with any complications, which are often reported with SCS (Deer, 2010).

Medical journals prefer the use of the third person and the active voice. Therefore, I adhered to this in the journal paper. However, for the extended paper I have used first person in line with how qualitative research is often written.

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<sup>4</sup> see [http://jns.msubmit.net/html/Instructions\\_to\\_Authors.pdf](http://jns.msubmit.net/html/Instructions_to_Authors.pdf) for instructions for authors.

## **1.2 Extended Introduction**

I reviewed the neuropathic pain (NP), chronic pain (CP) and SCS literature in order to gain a thorough understanding of the topics relevant to my research. The literature reviewed will be discussed and finally my rationale for the current research objective.

### **1.2.1 Neuropathic pain**

NP represents a heterogeneous group of pain conditions (Jensen, Gottrup, Sindrup, & Bach, 2001). It is defined by the International Association for the Study of Pain (IASP) as being 'initiated or caused by a primary lesion or dysfunction in the nervous system' (Merskey & Bogduk 1994, p. 212). The inclusion of the term 'dysfunction' has been critiqued for being too vague (Max, 2002) and alternative definitions have been suggested (e.g. Backonja, 2003), however for the purpose of this paper I shall use this definition as it is accessible and fit for the purpose of this paper.

### **1.2.2 Chronic pain**

Pain is a multifaceted, subjective experience, which involves physiological, affective, motivational and cognitive processes (Gybels et al., 1998). Acute pain may temporarily interrupt activities, however CP whether intermittent or continuous interferes with functioning (British Pain Society [BPS], 2009). Pain becomes termed as chronic when it has been experienced for six months or beyond what is expected for the course of normal healing (National Institute of Health and Clinical Excellence [NICE], 2008). Pain under this definition is perceived as a significant medical condition as opposed to a symptom (NICE, 2008). However, the research on CP does not always differentiate between chronic nociceptive pain (pain in response to an injury or tissue damage) and NP symptoms as a result of disrupted nerve functioning (Closs, Staples, Reid, Bennett & Briggs, 2009). Therefore, relevant research from the broader CP literature will need to be drawn upon which will include the NP

population. However, when I am referring specifically to NP research, this will be explicitly stated.

### **1.2.3 Epidemiology of Chronic Neuropathic Pain (CNP)**

A recent review conducted for the epidemiology of CP suggested that there continues to be no accurate estimate for the prevalence of NP in the United Kingdom (UK) population (Smith & Torrance, 2010). Prevalence rates have been difficult to estimate due to there not being a well validated and reliable measure to identify the characteristics of NP (Bouhassira, Lanteri-Minet, Attal, Laurent, & Touboul, 2008). In a UK primary care survey, the prevalence of pain of neuropathic origin was reported to be 8% in this general population (Torrance, Smith, Bennett, & Lee, 2006). However, the presence of NP is perceived to be under-diagnosed and under-treated (Taylor, 2006). It has become clear that CP with neuropathic characteristics is more common in the general population than previously suggested (Torrance et al., 2006). Furthermore, this type of pain is more severe than any other forms of CP and is amongst one of the most challenging conditions to treat, as it is less responsive to analgesic drugs (Dworkin et al., 2003).

### **1.2.4 Aetiology and clinical presentation of CNP**

NP is an umbrella term for a number of pain conditions. The most common types of NP are Failed Back Surgery Syndrome (FBSS), Complex Regional Pain Syndrome I & II (CRPS I & II) and Diabetic Neuropathy (see appendix A for descriptions and other NP conditions). All have different aetiologies and can be experienced in different locations (Sindrup & Jensen, 1999); however NP is predominantly experienced in the back and legs (Dworkin et al., 2003). It can be caused by infections, chemotherapy, surgeries, nerve compression and trauma (Dworkin et al., 2003). A distinction is often made between stimulus evoked NP and spontaneous NP that occurs independent of a stimulus persistently or intermittently

(Dworkin et al., 2003; Sullivan, Lynch, & Clark, 2005). The former can be brief, but can persist even after the cessation of the stimulation, whereas the latter is characterised by shooting, cramping or a burning like sensation (Jensen et al., 2001). Alternatively, it can be an episodic type pain like an electric shock or stabbing feeling (Jensen et al., 2001). The unpredictability and unpleasantness of the pain can be extremely distressing for those who experience it which has a negative impact on patients' quality of life (QoL; Closs et al., 2009).

### **1.2.5 Impact of chronic pain**

Health related quality of life (HRQoL) has consistently been reported to be reduced in people with various NP conditions (O'Connor, 2009) and in CP in general (Breivik, Coltett, Ventafridda, Cohen, & Gallacher, 2006). CNP has specifically resulted in reduced mobility and physical functioning, depression, and difficulties initiating and maintaining sleep (McCarberg & Billington, 2006). The difficulties with sleep are thought to exacerbate symptoms and reduce pain threshold which can result in anxiety and depression (Nicholson & Veman, 2004). However, the reverse can also occur, with anxiety and depression disturbing sleep, demonstrating the complex relationship between these variables (Nicholson & Veman, 2004). Consequently, many individuals experiencing CNP are less productive at work, become unemployed or have to take early retirement (McDermott, Toelle, Rowbotham, Schaefer, & Dukes, 2006).

The burden of NP goes beyond the person (O'Connor, 2009) impacting on families supporting them (Sofaer-Bennett, Walker, Lamberty, Thorp, & Dwyer, 2007) as well as wider society due to the burden on the economy (Brook, Georgy, & Olan, 2009). The financial burden is a consequence of people not being able to work

(McDermott et al., 2006), needing to claim benefits and having high healthcare costs (Manca et al., 2008).

### **1.2.6 Psychological factors involved in CP**

Pain is a fundamental aspect of human experience; it is an interruptive signal to alert an organism to potential danger, drawing our attention away from other competing stimuli (Eccleston, 2011). However, repeated interruption can lead to interference such as reduced performance or not completing jobs and tasks which is associated with frustration (Price, 1999).

Threat is understood to be central to the pain experience as it diverts individuals' attention to the cause of the pain and encourages escape, which is often achieved through analgesic medication (Eccleston, 2001). Attention to, and vigilance of pain have been identified as predictors of emotional distress, psychosocial disability and the use of health care resources (McCracken, 1997). This, alongside the beliefs about pain, particularly the appraisal of what the pain means has become a focus in the pain literature (Turk & Okifuji, 2002). Specifically, catastrophic thinking about pain, whereby individuals over exaggerate or magnify the perceived threat of pain, can leave individuals feeling helpless about controlling their symptoms (Thorn, Boothby, & Sullivan, 2002). Catastrophic thinking has been associated with depressive symptoms even after controlling for demographic information and pain severity (Richardson et al., 2009). This links into cognitive-behavioural understanding of CP. One such model employed to understand how individuals cope with their pain is the fear-avoidance model (see Leeuw et al., 2007 for review). It suggests individuals develop fear of particular movements/activities due to the anticipation of harm which results in avoidance (Morley, 2008). Prolonged avoidance of activities due to this fear, has led some authors to argue it is the fear

of pain that is more disabling than the pain per se (Waddell, Newton, Henderson, Somerville, & Main, 1993).

Another predominant way of coping with CP is to persist in trying to solve the problem. However, individuals are often faced with numerous failed treatments leading to disappointment (Morley, 2008). This type of coping has been referred to as an assimilative coping style, whereby active attempts are made to alter unsatisfactory life situations and restrictions (Schmitz, Saile, & Nilges, 1996). The alternative is accommodative coping which involves adapting aspirations and re-evaluating personal goals in relation to the losses and changes that have happened as a result of pain (Schmitz et al., 1996). The latter includes flexibility and adjusting to goals which is suggested to be important in preventing the development of depressive symptoms (Schmitz et al., 1996).

### **1.2.7 Treatment of CNP**

The first line and predominant treatment prescribed for CNP is pharmacological (Turk & Burwinkle, 2005). NP patients are offered a range of analgesics including opioid medications which can have debilitating side-effects and are only moderately effective (Turk & Burwinkle, 2005). A recent survey indicated that NP patients were more likely to be taking opioids alongside various other pain medications (Torrance et al., 2006). However, patients still reported inadequate pain relief (Torrance et al., 2006). The main difficulty in treating CNP with medication is being able to identify the specific NP mechanisms at play so that the most effective drug for that mechanism can be identified (Nicholson & Verma, 2004). Due to this being a difficult task, it often results in a trial and error approach with different medications, leaving patients feeling frustrated and disappointed (O'Connor, 2009).

An alternative form of pain relief is the use of regional analgesics, which involves having injections to numb the painful area for a short period of time (Turk & Burwinkle, 2005). Antidepressant medication has also been effective in providing pain relief in some people with NP (O'Connor, 2009). These often only provide partial relief (O'Connor, 2009), although they can be used to assist in treating depression in CP patients (Dworkin et al., 2003). Lastly, various anticonvulsant medications have been shown to be effective in treating different NP conditions (Jensen, 2002). Following these pharmacological treatments, corrective surgery is the next most common option offered to CP patients (Turk & Burwinkle, 2005). However, there are mixed results with some patients continuing to experience pain. Despite this inconclusive evidence it is still routinely employed and is associated with high costs to the healthcare system (Turk & Burwinkle, 2005).

Psychological treatments such as Cognitive Behaviour Therapy (CBT) have been shown to be effective in treating CP (e.g. Eccleston, Williams, & Morley, 2009; McCracken & Turk, 2002). CBT focuses on reducing pain and distress through modifying negative, catastrophic beliefs and changing unhelpful behaviours like avoidance of activities (McCracken & Turk, 2002; Wetherell et al., 2011). In contrast, Acceptance and Commitment Therapy (ACT) takes a different approach. ACT focuses on changing an individual's relationship to pain, encouraging them to learn to tolerate and accept their pain so their life values can be restored (Morley, 2008). This in many ways is in contrast to what we as humans instinctively want to do. We have not evolved to disregard signals of danger or ignore our pain as this would not only be counter-cultural, but counter-biological (Eccleston, 2011). However, equally, persistent seeking for a cure or trying to control pain has been argued to make it more central and disruptive to peoples' lives (Hayes & Duckworth, 2005) leading to disappointment and frustration at HCPs (Morley, 2008). ACT does

not aim to eliminate pain but can free individuals from the struggle of avoiding or reducing pain, becoming more aware of the current moment to pursue goals consistent with life values (Hayes & Duckworth, 2005; see Hayes, Jacobson, Follette, & Dougher, 1994, for more detailed discussion of acceptance). There is a growing evidence base supporting ACT as an effective treatment for CP (e.g. McCracken & Eccleston, 2003; McCracken, Vowles, & Gauntlett-Gilbert, 2007; Viane, Crombex, Eccleston, Devulder, & De Corte, 2004; Vowles, McCracken, & Eccleston, 2007). Although at present it is similar groups of authors investigating this concept.

The above treatments are recommended to be used simultaneously to treat CP in order to provide a more holistic care package treating sensory, affective and physiological aspects of pain (Turk & Oujiki, 2002). For more intractable NP conditions, when standard treatments have failed, patients can be offered SCS which will be discussed in more detail next.

In summary, CP has a significant impact on individuals' personal, social and occupational functioning. The experience of CP involves a range of psychological factors which impact on the experience of pain and coping strategies. There are a variety of treatments available, however often NP is resistant to such treatments resulting in multiple treatments being used simultaneously. When other standard treatments have failed to provide pain relief, more invasive procedures such as surgery are considered. One such option is SCS surgery.

### **1.3 Spinal cord stimulation surgery**

The therapeutic application of electrical stimulation to the spinal cord has been used to treat various pain disorders since 1967. However advances in surgical techniques and technology have increased its popularity over recent years (Falowski, Celii, & Sharan, 2008). The



goal of neurostimulation is to reduce the intensity, duration and frequency of pain, however not to eliminate it (Falowski et al., 2008). The trial prior to full implantation is an advantage of SCS. This can provide subjective observations from the patient in combination with other clinical evidence to determine suitability (North & Shipley, 2007). When implanted, patients use a remote control to adjust the amount of stimulation for pain relief. Another attractive feature of SCS is that it can be reversed. This is in contrast to other surgical procedures for pain relief, as these can change the patient's anatomy or rupture pain pathways (North & Shipley, 2007). SCS is currently recommended as an effective treatment for reducing CNP (NICE, 2008). However evidence for pain of other origins is equivocal (NICE, 2008). For example, the evidence is inconclusive for ischemic pain<sup>5</sup> with more robust studies being required (NICE, 2008).

### **1.3.1 Efficacy of SCS**

There is an extensive evidence base of SCS efficacy studies. However the methodological quality varies, with it predominantly containing case series and examples of clinical case studies related to technology. In contrast, over the last decade, more robust randomised controlled trials (RCT) have been undertaken. Two RCTs investigated SCS for CNP, one with FBSS patients (Kumar et al., 2007, 2008) and one with CRPS patients (Kemler et al., 2000; Kemler et al., 2004, 2008). Results indicated that SCS was effective at reducing pain in both NP conditions in comparison to baseline results and control groups, at six and 12 month follow-ups. FBSS patients showed improvements in HRQoL, functional capacity, reduction in medication use and greater patient satisfaction at six and 12 month follow-up (Kumar et al., 2007, 2008). Whereas CRPS patients showed initial improvements in pain relief and HRQoL at 6 and 24 month follow-ups, however these were not sustained at the 60 month follow-up (Kemler et al., 2000; Kemler et al., 2004, 2008).

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<sup>5</sup> Ischemic pain is pain resulting from insufficient blood flow for the metabolic needs of organs.

A more recent retrospective evaluation of SCS efficacy for CRPS I demonstrated SCS improved pain, HRQoL and functional status (Kumar, Rizvi, & Bnurs, 2011). Interestingly, although the last follow-up scores at 88 months were lower than baseline, they were higher than at 12 month follow-up which is consistent with previous trials (e.g. Kemler et al., 2008) suggesting there is often a reduction in pain relief over time in patients with CPRS I. Of note, some trials were funded by companies who manufacturer the stimulators (e.g. Kumar et al., 2007, 2008). It is important to acknowledge the potential bias however measures were taken to reduce this.

Clinical trials and case series employ a range of outcome measures to evaluate the different aspects of the pain experience. The standard measure for pain relief is using a visual analogue scale (VAS) containing statements to quantify pain relief, or through percentages ranging from 0-100% that can be rated before and after the surgery (Doleys, 2006). Through evaluating studies this way, researchers gain a breadth of information, however they work on the assumption that individuals' pain is quantifiable into a rating or percentage that will reflect their experience of pain (Simpson, 1997). Furthermore, when considering HRQoL tools used such as the EuroQol-5D (Kind, 1996), it provides mild, moderate or severe ratings for severity on five dimensions of life (mobility, self care, ability to undertake usual activity, pain/discomfort, and anxiety and depression), however it provides little detail of the meaning of experience to the patient, nor the influence of their social and cultural context on the pain experience. As Simpson (1997) proposed, the categorisation of outcomes can be over-simplistic given that pain can vary over time, place and circumstances. Certainly none of the methods reviewed explicitly captured any in-depth meaningful psychological experiences of life before or after SCS surgery. This is an important consideration, as Eccleston (2001) asserts 'for all patients with pain, what is understood about the meaning of pain,

disease and/or disability will play a part in the presentation of the problem and the effectiveness of treatment' (p. 144).

Furthermore, measures of patient satisfaction have employed similar structured questions to evaluate patients' perspective of SCS. Although this has yielded some interesting data, it again limits the response patients can provide. Interestingly, despite patients finding they experienced a reduction in pain in the Kemler trial, 18 of the 20 (90%) remaining implanted patients at five years follow-up indicated a positive response to treatment and 19 patients (95%) expressed they would undergo SCS again for the same result (Kemler et al., 2008). It would be interesting to understand exactly what the SCS meant to these patients given they continued to provide positive feedback despite the SCS not maintaining its primary function of pain relief. Or this raises the question of whether the values provided on the outcome measures were not a true reflection of their SCS experience.

In summary, there is a lack of in-depth data about how individuals make sense of their SCS experience or their satisfaction with the treatment. Specifically, the research fails to explore psychological factors with alternative methods to questionnaires, therefore potentially limiting the depth of data yielded. There is a need for research in this literature to explore process as oppose to solely focusing on adjustment outcomes.

### **1.3.2 Psychological factors and SCS**

The role of psychological factors in SCS surgery has been a focus over the last couple of decades (see Beltrutti et al., 2004; Doleys, 2006; Sparkes et al., 2010). Research indicates the importance of patient preparation prior to SCS, particularly determining patients' expectations and psychological stability, as both can have a negative impact on SCS outcomes (Doley, 2006). In light of negative emotions

accompanying pain, it is important to distinguish emotions associated with CP and those reflective of unresolved major psychiatric disorders (e.g. severe depression, psychosis) which are contraindications for SCS (Gybels et al., 1998). Psychopathology in terms of extreme personality characteristics that impact on general life functioning have also been discussed as important to recognise prior to SCS surgery (Beltrutti et al., 2004). Therefore, psychological testing during patient screening for SCS is recommended by NICE (2008), and the IASP Guidelines for neuromodulation (Gybels et al., 1998). At present, there is insufficient evidence to determine whether psychological screening improves SCS outcomes (Celestin, Edwards, & Jamison, 2009). However, pre-surgical depression, anxiety, somatisation and poor coping have been predictive of poorer SCS outcomes (Celestin et al., 2009). Despite this, there is no standard measure for assessment (Sparkes et al., 2010) and psychological assessment does not appear to be consistently applied in practice in the UK (Ackroyd, Bush, Graves, McVey, & Horton, 2005). A common measure employed is the Minnesota Multiphasic Personality Inventory which deciphers behaviours and expressions of pain that could be attributed to psychological distress and patient personality (Beltrutti et al., 2004). Predominantly, it is high scores of the depression scale of this measure which have been indicative of reduced SCS efficacy, however equally depression is a variable shown to improve post-SCS (Sparkes et al., 2010). Therefore, it is suggested depressive symptoms should not be an exclusion criterion for SCS (Beltrutti et al., 2004; Sparkes et al., 2010). It is the severity and impact of such symptoms that should be assessed with interviews alongside questionnaires so they can be treated prior to (Beltrutti et al., 2004) or alongside SCS therapy (Sparkes et al., 2010).

It is hypothesised that psychological factors could account for the loss of analgesia in some patients, 12-24 months after SCS surgery

(Doleys, 2006). Monhemius and Simpson (2003) advocate the loss of effectiveness may be a consequence of patients underestimating the pain relief gained. They discovered that loss of functioning in the device demonstrated to some patients that their stimulator was more effective than appreciated. This is an important consideration as it highlights how much more there is to discover about the experience of this surgical procedure, especially given the high costs associated with the surgery (Turk & Burwinkle, 2005).

Of note, there is a dearth in the SCS literature of qualitative analysis of significant psychological experiences and concepts that have been identified as important in the CP literature. For example, a person's sense of self or identity (Smith & Osborn, 2007), the experience of the healthcare system (Walker, Holloway, & Sofaer, 1999), living with and managing NP symptoms (Closs et al., 2007) and the embodied experience of pain (Bullington, 2009) which could have important implications for subsequent rehabilitation.

In summary, literature indicates certain psychological variables can impact on SCS outcomes providing insights for patient suitability and psychological assessment. However, with this predominant focus on psychological factors for assessment and related to outcomes, research has failed to capture the significance and complexity of the psychological processes involved in the lived experience of CNP and having an implantable device.

#### **1.4 The lived experience of chronic pain and implantable devices**

Qualitative methods exploring the experience of living with CP have provided rich data on individuals' sense of self and identity (Osborn & Smith, 2006; Smith & Osborn, 2007), experiences of loss (Walker, Sofaer, & Holloway, 2006) and feeling disempowered by the healthcare system (Walker, Holloway, & Sofaer, 1999). Qualitative

methods have also provided insights into the experience of adapting to living with an implantable device. This section will summarise significant concepts that are discussed in this literature.

#### **1.4.1 The self and identity**

The literature uses terms such as self concept, sense of self and identity interchangeably (Osborn & Smith, 2006). However in line with Osborn and Smith (2006), for the purpose of this study, these terms will refer to a 'stable but dynamic collection of core beliefs, constructs, affects, or cognitions that are utilised by the individual to define themselves both privately and in their presentation to the outside world' (p. 216). The experience of prolonged suffering like CP is perceived as a challenge or threat to identity (Ecclestone, Williams, & Stainton-Rogers, 1997). Such experiences have been described as 'living with a body separate from the self', whereby painful parts of the body are excluded from the preferred self and classified not as a part of the individual (Osborn & Smith, 2006, p. 216). This disparity between the painful body and preferred self is proposed to prevent rehabilitation and acceptance of this new part of their identity (Smith & Osborn, 2007). The impact of pain on patients daily functioning is extensively talked about in studies on chronic lower back pain (CLBP). This research describes patients feeling vigilant and aware of movements resulting in them no longer feeling capable and productive (Crowe et al., 2010). The losses experienced as a result of functional difficulties negatively impacted on individuals' confidence and a divide transpired between how patients saw themselves and who they wanted to be (Crowe et al., 2010). These experiences have resulted in patients perceiving pain as an uncontrollable threat, associated with a loss of independence and social and family roles (Snelgrove & Liossi, 2009).

### **1.4.2 Being caught up in the healthcare system**

This experience of alienation and detachment from the pre-pain self and things that used to give the individual meaning are also apparent between CP patients and people without CP (Bullington, 2009). Themes within the literature indicate individuals seeking help from pain clinics, felt insignificant, poorly understood and dismissed, being thrown from service to service (Walker et al., 1999). Therefore, patients not only felt let down by their bodies (Snelgrove & Liossi, 2009) but also by services, leaving them feeling trapped by the healthcare system (Walker et al., 1999). Consistent across studies was the desire to make sense of the origins of the pain (Osborn & Smith, 1998) through obtaining a diagnosis however, this did not always happen, leading to frustration (Walker et al., 1999). Furthermore, literature suggests CP patients often felt they were not believed by professionals (Snelgrove & Liossi, 2009) which has been attributed to the lack of visibility of illness, leading them open to labels such as being malingers (Clarke & Iphofen, 2005).

### **1.4.3 Living with an implant**

Exploratory qualitative research has provided significant insights into the psychological impact and experience of other surgically implanted devices such as Implantable Cardioverter Defibrillators (ICDs; Deacon, Dunbar, Moloney, Sear, & Ujhelyi, 2003; Hallas, Burke, White, & Connelly, 2010; Tagney, James, & Albarran, 2003). This treatment is for patients with atrial fibrillation or ventricular arrhythmias which is when the atria or ventricles of the heart have an irregular rhythm (Deacon et al., 2003). These devices issue electrical shocks to the heart either automatically when there is an irregular heart rhythm or when the patient activates the device (Deacon et al., 2003). Although, the function of this implant is very different to SCS, patients with a SCS also need go through the physical and psychological adjustment to having an implant. Interestingly, the data yielded suggest a similar experience to chronic pain patients with

their pre-implant life consisting of misdiagnosis, minimisation of symptoms, distressing impact of symptoms such as activity reduction and continuous pursuit of treatments (Deacon et al., 2003). However, there were methodological limitations of the study as the methodology employed was unclear. In contrast, two other studies employed grounded theory and provided adequate information about the analytic procedure. One study indicated being in control of the illness, decision making, and ICD issues were the most significant to participants (Hallas et al., 2010). The other study also found issues relating to control, both losing it and regaining it (Morken, Severinsson, & Karlsen, 2009). The loss of control was due to the unpredictability of the shocks on the automatic devices; then regaining control was related to life after a shock (Morken et al., 2009). Participants in this study also talked about adjusting to the device and eventually changing the way they felt about it, accepting the uncertainty. There was also a focus on having to seek support and not feeling they had received enough information about the impact it would have on their daily lives (Morken et al., 2009). These studies provided a wealth of information about what it is like for patient living with an ICD. Such rich data is currently absent in the SCS literature.

### **1.5 Rationale**

The lack of in-depth analysis of patients' psychological experience of SCS surgery highlights the importance of conducting exploratory qualitative research to inform existing quantitative studies. The SCS literature has provided insights into SCS efficacy for a number of different forms of CP as well as different types of NP. Recent systematic reviews suggest SCS can reduce pain, improve HRQoL and functional status in NP conditions (e.g. Simpson, Duenas, Holmes, Papaioannou, & Chilcott, 2009). There is also a body of literature on the role of psychological variables informing assessment processes and patient selection to improve SCS outcomes. However,



there is little understanding of the complex relationship between pain, the patients' bodies, their sense of self and identity and general experience of the treatment journey of SCS surgery. Therefore, I aimed to contribute further to this evidence base by exploring the lived experience of the patient's treatment journey of SCS with consideration to how they make sense of their experience of life with CNP prior to, and post SCS implant. This approach is in line with creating a more patient led National Health Service (NHS), giving a voice to patients who hold knowledge and understanding of the experience of CNP and SCS (Department of Health [DoH], 2005). I hope the research can increase multidisciplinary pain management teams' understanding of the experience of having SCS surgery, informing future practice and providing information for future SCS candidates.

## **2.0 Extended Method**

The following information is an extension of the method section in the journal paper. This includes a discussion of quantitative and qualitative methodologies, an appraisal of different qualitative approaches, a comprehensive rationale for adopting Interpretative Phenomenological Analysis (IPA; Smith, 1996) and further details of the procedure, data collection and analysis.

### **2.1 Quantitative and qualitative research**

It is beyond the scope of this paper to provide a historical account of the development of, and divergences between quantitative and qualitative modes of enquiry. However in order to contextualise the current research, a brief overview will be provided, detailing related philosophical underpinnings.

A researcher's perspective on the nature of reality (ontology) and what can be known (epistemology) will inform how they attempt to attain knowledge (methodology). At one end of the spectrum, there is the naive realist ontology. This perceives there is an objective reality that can be apprehended. This informs a positivist epistemological position, where the object of scientific enquiry is seen as independent of the researcher. Knowledge is gained through testing pre-determined hypotheses through direct observations and measurement which can then be subjected to statistical analysis (Krauss, 2005). However, for the majority of quantitative researchers, the focus changed over time from verifying (positivism) to falsifying (post-positivism) hypotheses (Guba & Lincoln, 1994). Therefore, some quantitative researchers started to consider an element of interpretation in the production of knowledge (Madill, Jordan, & Shirley, 2000). This is more consistent with a critical realist stance which perceives there to be a reality, but that there are multiple perspectives of this reality (Healy & Perry, 2000). Critical realism lends itself well to both quantitative and qualitative methods of

enquiry. At the other end of the ontological spectrum<sup>6</sup>, there is the relativist position which advocates there is no single true reality (Ponterotto, 2005). Rather, there are multiple, constructed realities that are influenced by historical, social and cultural factors. This ontological position informs a range of constructivist and interpretative epistemologies which acknowledge the dynamic relationship between the researcher and participant (Ponterotto, 2005). Qualitative methods are concerned with gaining participants' perspectives and understanding phenomenon as they occur in particular situations (Carter & Little, 2007; Yardley, 2000). Such methods can be informed by various epistemological positions. Therefore, it is important that I am transparent about my position on reality and what can be known from that position in order to demonstrate how this informed my choice of IPA to explore my research objective.

## **2.2 Epistemological position**

I adopt a critical realist position, whereby I perceive there to be stable and enduring features that make up an underlying reality, but understand there can be multiple perspectives and meanings related to this reality (Fadde, 2004). I perceive these as being mediated by the thoughts, expectations and beliefs that individuals bring to it (Willig, 2008a). Therefore, I accept that past experiences will inevitably influence what people say and do, applying to me as the researcher, as well as my participants. I think it is important to be critical of what we think we know and I recognise that we can only try to access reality. Within critical realism, reality is perceived to be arranged on a number of levels. Therefore, scientific investigation must go beyond 'statements of regularity', analysing the underlying processes and meanings that can explain the patterns generally observed (Denzin & Lincoln, 2011, p. 11). For this reason, and due to the existing SCS literature, I felt a qualitative method of enquiry was more appropriate.

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<sup>6</sup> It is important to note that there are certain perspectives that propose to be a-ontological such as functional contextualism (see Hayes, 1993, for further details).

These would enable me to gain an understanding of the meaning of the experience of SCS, whereas quantitative methods would only contribute to the already existing generalised patterns available within the SCS literature.

### **2.3 Qualitative rationale**

Building on from the previous section, the existing SCS literature provides a breadth of understanding relating to SCS efficacy, technology and patient suitability. However this approach fails to take healthcare professionals (HCPs) to the core of patients' lived experience (Biggerstaff & Thompson, 2008). Patient satisfaction has been investigated using structured questions focusing on satisfaction with pain relief and whether patients would have agreed to this treatment based on their outcome (e.g. Kemler et al., 2008; Kumar et al., 2007; Ohnmeiss & Rashbaum, 2001). The results of other more in-depth interviews have been ranked or quantified (e.g. Anderson, Carlson, & Shatin, 2001; Devulder, DeLaat, Bastelaere, & Rolly, 1997). This type of research fails to account for process and is more focused on outcomes. Therefore, it cannot capture past experiences and events surrounding patients' SCS choice. To gain a greater understanding of patients' subjective experience of SCS surgery, a methodology that would capture the depth of participants' sense making of their experience was required. This would enable acknowledgement of the process, giving patients the opportunity to speak about what was important and meaningful to them. Therefore, employing a quantitative framework and issuing questionnaires would not have been appropriate for this objective.

### **2.4 IPA**

Prior to providing my rationale for IPA, this section will provide details of the background of IPA. IPA was developed by Jonathan Smith (1996) with the aim of examining how individuals make sense of their significant life experiences. He described IPA as mediating the

opposing positions of social cognition, where verbal responses were seen as reflections of cognitions, and discourse analysis (DA) where this idea was rejected, asserting talk is contextual (Smith, 1996; see *section 2.5.2 for further details on DA*).

IPA can be described as having a short history. However, its theoretical underpinnings in phenomenology and hermeneutics provide it with historical roots (Eatough & Smith, 2008). Phenomenology encourages exploration of the existential claims and concerns of individuals' experiences, whereas hermeneutics provides a critical interpretation of the meaning of individuals' accounts within their wider social and cultural context (Smith, 2004), thus understanding the 'person-in-context' (Larkin, Watts, & Clifton., 2006, p. 108). Therefore, IPA considers both personal meaning making and the social negotiation of meaning in the individuals' social world, thereby drawing on ideas from symbolic interactionism (Smith & Osborn, 2008).

#### **2.4.1 Phenomenology**

Phenomenology was initiated by Edmund Husserl in the early twentieth century (Giorgi & Giorgi, 2008). It is concerned with human experience in particular contexts and at particular times, as opposed to general assertions about the world (Willig, 2008a). IPA draws on Husserlian phenomenology, particularly his aim to go 'back to the things themselves' (Husserl, 1913/1982, p. 35). This allows 'experience to be expressed in its own terms', rather than attempting to fit experience into predefined categories (Smith, Flowers, & Larkin, 2009, p. 32). In Husserl's pursuit to return to the things themselves, he advocated that in order to get to this essence of a phenomenon, people are required to bracket any preconceptions about the object, in order to see it for what it is, as opposed to what they think they know about it. Conversely, IPA acknowledges that it is not possible to bracket such information and that a researcher's view of the world

will impact on the exploration process (Willig, 2008a). It is the acknowledgement of the role of the researcher in the research process that links the 'P' of IPA to the 'I' through drawing on hermeneutic traditions.

### **2.4.2 Hermeneutics**

Hermeneutics is the theory of interpretation (Smith et al., 2009). IPA advocates that researchers engage in a double hermeneutic, as they try to make sense of participants making sense of their experience (Smith & Osborn, 2008). It recognises that researchers can only attempt to access participants' personal world (Smith, 1996), as access is dependent on participants' ability, as well as their wish to express their thoughts and feelings (Smith & Osborn, 2008). This is also complicated by the researcher's perceptions, which as previously mentioned are an integral part of the interpretative process (Smith, 1996). This draws on Heidegger's hermeneutic phenomenology, as Heidegger critiqued Husserl's theories as abstract due to interpretation being inherent in understanding phenomenon and bracketing preconceptions being unachievable (Heidegger, 1999).

### **2.4.3 IPA rationale**

IPA was in line with my critical realist epistemological position, in its appreciation that individuals can experience the same event in different ways; dictated by their individual beliefs and expectations (Willig, 2008a). IPA's focus on lived experience has led researchers to explore chronic illness and the meaning made from such experiences, as it becomes an integral part of a person's life world (Smith, 2011). Therefore, I felt the topic of SCS for CNP lent itself well to IPA inquiry as recognising the meaning of pain is argued to be central to treatment success (Eccleston, 2001). A recent evaluation of the corpus of IPA studies, highlighted how the experience of

illness has been a dominant topic of inquiry; with CP and neurology being the most prevalent areas of research (Smith, 2011).

Additionally, IPA is distinct in offering both a strong theoretical underpinning alongside practical and accessible guidelines (Brocki & Wearden, 2006). These are seen as attractive to less experienced researchers (Smith et al., 2009) like myself. However, it has been criticised for being 'one recipe to guide analysis' (Braun & Clarke, 2006, p. 78), which seems a rather concrete interpretation of what is seemingly a suggestion to aid novice researchers. Recommendations are explicit in IPA articles that researchers should adapt and develop these guidelines as their research unfolds (Smith, 2004).

IPA also offers professionals a foundation for intervention through integrating research to practice, whereas some other methods, like discursive approaches, can have difficulty in achieving this integration with the predominant focus being on the function of language in specific contexts (Reid, Flowers, & Larkin, 2005; see *section 2.5.2*). Making such links was pertinent in the current study in order to inform professionals and future SCS patients of the patient perspective which thus far, has been neglected.

## **2.5 Different qualitative methods**

In this section, I aim to build a further argument of why I chose IPA as opposed to an alternative qualitative approach. There are various qualitative methods with differing, yet 'overlapping epistemological underpinnings as well as theoretical and methodological emphases' (Smith, 2004, p. 40), however only a selection will be outlined here.

### **2.5.1 Grounded Theory (GT)**

GT was originally developed by Glaser and Strauss in 1967. It contains both positivist and interpretative elements, using systematic

techniques, alongside exploring how individuals construct meanings, intentions and actions (Charmaz, 2008). However, over time a number of variants have developed with different epistemological underpinnings (Mills, Chapman, Bonner, & Francis, 2006). Common to all approaches, is the exploratory, inductive nature which focuses on theory generation. The aim of my research was to explore the unique lived experiences of those who have undergone SCS surgery, not to develop a theory on this process. Therefore, I did not see GT as an appropriate methodology.

### **2.5.2 Discourse Analysis (DA)**

DA is argued to be more than a research method. It challenges the understanding that language indicates individuals' underlying beliefs, attitudes and intentions. Instead it proposes that individuals use language to construct a version of their social world, thereby perceiving language to serve a function, which can vary depending on the context (Potter & Wetherell, 1987). DA has evolved over time and there are now a number of different strands, however they all hold a similar interest in the role that language plays in the construction of social realities (Willig, 2008b). The aim of the current research was to gain insight into how participants made sense of their SCS experience, as opposed to solely the linguistic resources employed to convey their accounts. Although IPA also has a linguistic element, the rationale is different, as it aims to explore the connection between embodied experience, how this is talked about, and made sense of, and the emotional responses to the experience (Smith, 2011). Therefore, the linguistic element is part of a much wider objective, which was more appropriate for my research with the strong experiential quality. However, most importantly, DA was not in line with my epistemological position as it aligns with a relativist ontology perceiving there to be multiple constructed realities.



### **2.5.3 Thematic Analysis (TA)**

TA is a method employed to identify, analyse and report patterns within data (Braun & Clarke, 2006). It has been suggested that TA holds the core skills for all qualitative analyses and therefore should be learnt prior to engaging in other forms of qualitative research (Braun & Clarke, 2006). Braun and Clarke (2006) highlight that when using TA researchers are required to make a number of decisions prior to beginning. If researchers have a theoretical interest to pursue, they are likely to take a top down approach. Those wanting to take a more exploratory approach are more data driven, taking a more inductive bottom up approach. There are also two different levels of analysis in TA. The semantic level focuses primarily on the form and meaning of what the participant has said. In contrast, latent analysis examines the ideas and assumptions, theorising what may have shaped the semantic data (Braun & Clarke, 2006). Therefore, taking an inductive approach using a latent analysis could be argued to be very similar to IPA, the main difference being that TA does not stem from a particular theoretical underpinning (Braun & Clark, 2006). Furthermore, similar to IPA, TA can be employed by those closer to a realist (e.g. critical realists) ontological position, as well as those working from a more relativist end of the spectrum (e.g. constructionists). The decision not to use TA was less about why TA was not appropriate and more to do with IPA being seen as more appropriate due to its phenomenological and hermeneutic roots which were key to understanding the meaning of lived experience of SCS surgery. Although TA, like other qualitative methods, does acknowledge the role of the researcher, there is less of an emphasis on this. I was drawn to how IPA explicitly acknowledges the double hermeneutic between researchers and participants, as well as the hermeneutic circle occurring during interview, analysis and write up (Smith et al., 2009). This was felt to be more in line with my epistemological underpinnings and beliefs than TA.

### **2.5.4 IPA critique**

I previously referred to IPA having a linguistic element and described the breadth of objectives within the IPA rationale [see section 2.5.2]. However, it could be argued that in covering such breadth during the analysis (description, linguistic, conceptual interpretations), an element of the depth is likely to be lost. This is supported by indications that novice qualitative researchers make basic social comparison as opposed to an in-depth analysis (Smith, 2004). Although, equally I would argue the more you use IPA, the more you will develop the analytical skills. Furthermore, it could be argued IPA brings too many theoretical underpinnings together making it difficult to do justice to each part.

Despite these shortcomings, I felt that IPA was most appropriate for the research objective. In contrast, I was drawn to the theoretical underpinnings that focused on interpreting lived experience as well as the idiographic commitment of IPA and felt this was most appropriately aligned with my experiential focus of exploring the unique experiences of SCS surgery.

## **2.6 Participants**

### **2.6.1 Purposive sampling**

Purposive sampling is the selection of participants based on their group membership or experience of a phenomenon relevant to the research objective (Holloway & Wheeler, 2010). This is consistent with IPA where participants are employed for representing a perspective as opposed to a population (Smith et al., 2009). Therefore, the aim of the current study was to explore these perspectives in depth, as opposed to obtaining data to be generalised to a specific population.

### **2.6.2 Homogenous sample**

A relatively homogenous sample is advocated for IPA research (Smith et al., 2009). This was achieved through purposive sampling as previously described. However, it is important to consider this concept of homogeneity. Although the current sample was homogeneous in that all participants had undergone SCS surgery for CNP, other characteristics differed such as the origin of their pain, their age, sex and previous treatments. The aim was not to treat the participants as the same, as I also wanted to capture the psychological variability in the group, through exploring the convergences and divergences between participants' experiences (Smith et al., 2009). Homogeneity in a sample can focus exploratory research, yet it could be argued that too much homogeneity could constrain the findings. Therefore, I think employing participants who had undergone SCS surgery at the same hospital, within a specific time frame, was sufficiently homogenous for the research objectives.

### **2.6.3 Sample size**

For professional doctorates conducting IPA research, four to ten interviews are recommended (Smith et al., 2009). The use of a small sample allows for a strong idiographic commitment, so that a detailed, nuanced analysis of each case can be undertaken before cross-case analysis (Smith, 2004). Therefore, it is recommended that novice IPA researchers avoid employing larger sample sizes, where the vast amount of data generated can become overwhelming and jeopardise the depth of the analysis (Smith & Osborn, 2008).

Based on the estimated participant pool of 15-20 patients, I aimed to recruit between eight to ten participants. This sample size was chosen based on the estimated participant pool and the surgeon's perception that there would be a high response rate. However, prior to and during the recruitment period from December 2010 to April 2011, fewer surgeries were performed reducing the participant pool.

Therefore, a substantial amendment was made to the study protocol inclusion criteria, to increase the potential participant pool. Originally participants who had undergone SCS surgery 4-8 months previously were eligible for the study. However this was extended to 2-8 months *[see section 2.7.1 for further details]*. This allowed for a period of post-surgery recovery, but was a short enough time scale for participants to recall life leading up to and after the surgery.

## **2.7 Participant recruitment**

### **2.7.1 Procedure**

Following gaining single-site ethical approval (see appendix I) and NHS R&D approval (see appendix J), I commenced the recruitment process in November 2010. To introduce the study to potential participants, information packs were sent out by the Department of Neurosurgery on my behalf (see Figure 1: Recruitment flowchart). Therefore, no personal information was accessed prior to participants' contacting me and agreeing to take part in the study. The pack included a covering letter (see appendix K) and a patient information sheet (see appendix L). The covering letter provided an overview of the research and highlighted it was being conducted as part of my training to become a Clinical Psychologist. The patient information sheet provided a detailed explanation of the objectives of the study, the participant's role, details of the interview, and a description of participant's ethical rights.

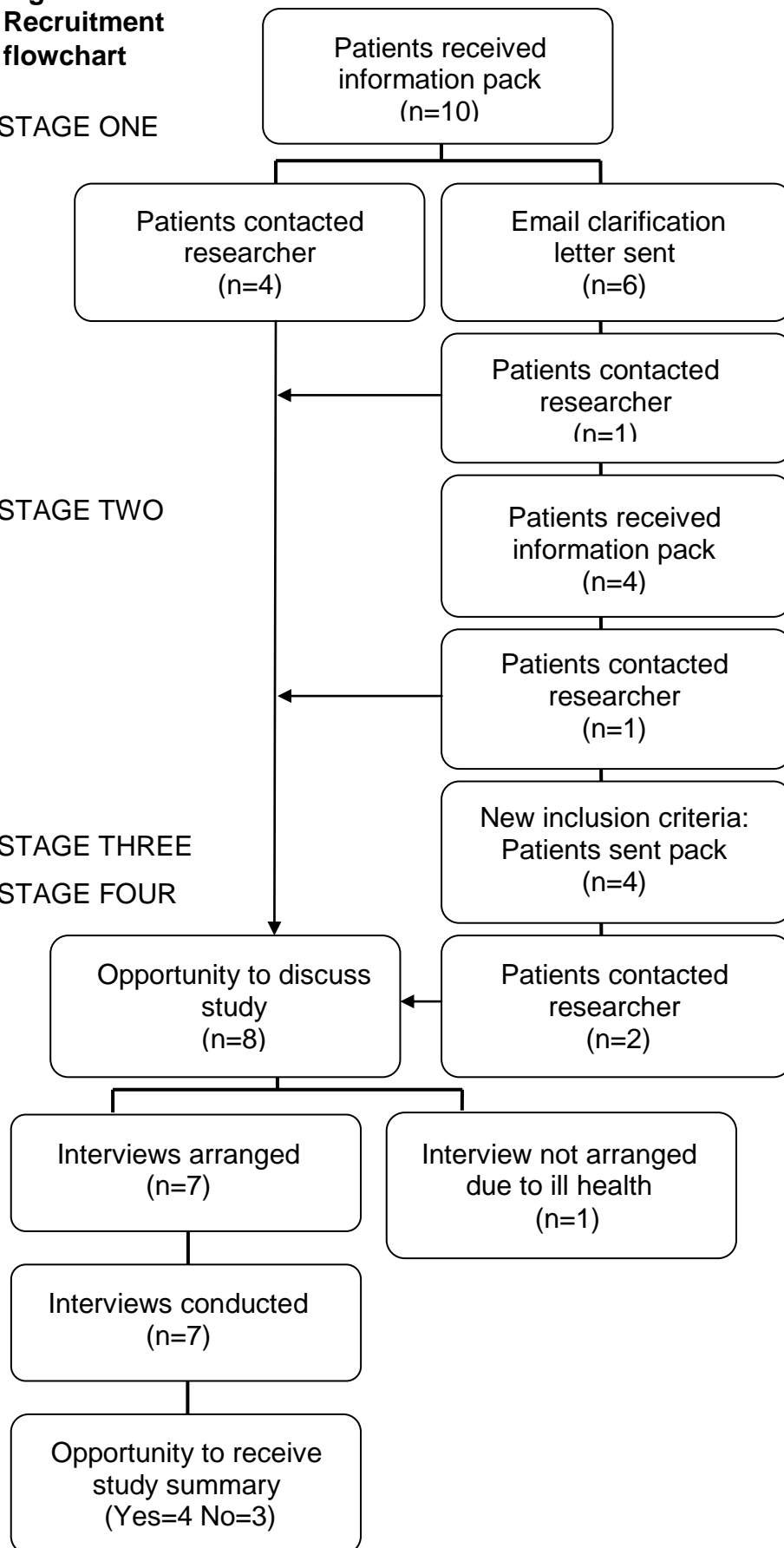
**Figure 1:  
Recruitment  
flowchart**

STAGE ONE

STAGE TWO

STAGE THREE

STAGE FOUR



### ***Stage One***

Ten information packs were initially sent to potential participants, however there was a low response rate (n=4). During this process it was brought to my attention that there was some confusion over the email address on the patient information sheet, where the lower case 'L' was being mistaken for a capital 'i'. Therefore, a minor amendment was submitted and approved by ethics (see appendix M:A) and R&D (see appendix M:B) allowing the Department of Neurosurgery to send an additional letter to potential participants previously contacted. This letter clarified the email address (see appendix M:C). This resulted in the recruitment of another participant.

### ***Stage Two***

Four more information packs were distributed to eligible patients, resulting in another participant agreeing to take part. Given that an adequate sample had not been obtained and no more patients fitted the inclusion criteria, a substantial amendment was made to the study protocol as previously stated.

### ***Stage Three***

Following gaining ethical (see appendix N:A) and R&D approval (see appendix N:B) for the substantial amendment, a further four information packs were sent to patients meeting the new inclusion criteria. Two more participants were recruited, resulting in a total of eight participants.

### ***Stage Four***

Following contact from the potential participants, I provided further details about the study over the phone and they were given the opportunity to ask questions. Following agreement to take part, participants were given the choice to have their interview before or after their neuromodulation appointment at the hospital or in the

comfort of their own home. The neuromodulation appointments are scheduled 4-8 months post-surgery and last approximately 15-20 minutes. It is provided to make any adjustments to the patient's stimulator and ensure they are gaining optimal pain relief. This option was provided so patients would not be making any extra trips as a result of taking part in the study. All but one of those who made contact opted to have the interview at their home. One patient expressed a preference to not have the interview at home. However he had already had his neuromodulation appointment, so this was not an option. He had recently had his SCS removed due to complications, but he still met the inclusion criteria. The patient agreed to have a telephone interview, however during preparation for applying to ethics for this amendment, the patient reported being very unwell. Therefore, I discussed this with the patient and we decided given the time it would take for ethical approval and the current severity and uncertainty surrounding the patient's ill health, it would not be appropriate nor ethical to undertake the interview. Upon making this decision, the patient appeared relieved, which reinforced this was the most appropriate course of action.

## **2.8 Data collection**

All participants were contacted the day prior to the interview to confirm the time, date and location and to ensure they still wanted to take part. On the day of the interview, the purpose of the study was reiterated to participants and the opportunity to ask question was again provided.

I spent time going through the consent form (see appendix O), explaining each section to participants before obtaining written consent [*see section 2.9.1. for further discussion on informed consent*]. The process of using the Olympus DS-55 digital voice recorder was described and a sound check was completed. Participants were also informed they could stop the interview to take

a break, adjust their stimulator or to withdraw from the study. I collected the information on the demographic data sheet (see appendix P) and then proceeded with the interview schedule (see journal paper).

Following the interview, participants were thanked for their involvement and given the opportunity to ask questions. I offered participants some leaflets with details of support services (e.g. Samaritans) as well as the Patient Advice and Liaison Service. They were also left with the contact details of the clinical psychologist in the research team and advised to contact their General Practitioner if they required any post interview support. Lastly, participants were offered the opportunity to receive a summary of the study. Four participants signed the study request form (see appendix Q), whereas the remaining three participants declined this offer.

For each of the interviews, I followed the lone working policy of the University of Nottingham and the NHS Trust Lone Working Policy. This entailed informing a member of university staff and my clinical supervisor who works for the hospital trust, of my whereabouts both prior to and after each interview.

### **2.8.1 Interview**

I employed face-to-face interviews to gather more in-depth descriptions of participants' life worlds and to allow interpretation of the meaning of the described phenomena (Kvale, 1983). These were chosen over telephone interviews, as face-to-face interviews allowed observation of social cues. These included voice intonation and body language (Opdenakker, 2006); helping to put their descriptions into context for when analysing the data. I felt that meeting participants face-to-face aided the researcher/participant relationship, which was particularly important given the sensitivity of information discussed. Although focus groups have been employed when using



IPA (e.g. Flowers, Knussen, & Duncan, 2001), I wanted to capture participants' idiographic account of their experience. I felt that using focus groups may have influenced what, and how much people disclosed. Given they were face-to-face interviews, I felt it was beneficial to have the interviews in the comfort of their own home. This way, their identity could remain anonymous to others, which would have been more difficult in a hospital setting. Although, I did feel it was important to give participants a choice.

### **2.8.2 Semi-structured interview schedule**

IPA literature suggests employing a semi-structured interview schedule to guide the interview process (Smith et al., 2009; see journal paper). However, this is not intended to be prescriptive (Biggerstaff & Thompson, 2008). During the development of the interview schedule, I consulted existing literature on CP and SCS alongside previous studies that had used IPA semi-structured interviews (e.g. Smith & Osborn, 2007). Following discussions with clinical and research supervisors, I produced a final interview schedule. I then liaised with members of the public to ensure the schedule was accessible and easily understood.

The interview schedule followed a chronological sequence to explore the treatment journey comprehensively. I felt it was important to contextualise their SCS experience by understanding what had led participants to choose this treatment option. As suggested by Smith et al. (2009), I employed open ended questions alongside a mixture of the following: description questions (e.g. describing life before and after the surgery); evaluative questions (e.g. related to feelings about the experience of pain and suggestion of SCS surgery); comparative questions (e.g. exploring if the experience of pain and the surgery had changed the way the participant felt about themselves); and prompts (e.g. can you tell me more about that?). Prior to the interviews, I had learnt the schedule to avoid distracting the

participant by reading the questions. I also used prompts when interesting claims or concerns were raised.

### **2.8.3 Contextualising interview**

Notes were made during the interview and afterwards, to provide initial reflections and observations (Smith et al., 2009). They not only acted as a reminder of topics I wanted to return to during the interview, but allowed me to document when there were changes in a participants' participation or if they were referring to items in the room such as the remote for the stimulator. This contextualised the topic under discussion and acted as a prompt when transcribing and analysing the data. I also found that having demographic information (e.g. about past operations and current medications) helped to contextualise the content of participants' accounts.

## **2.9 Ethical considerations**

Ethical approval was sought and granted from the Leicestershire, Northamptonshire & Rutland Research Ethics Committee 1 (LNR REC 1; see appendix I) and the University of Nottingham. R&D was sought and approved by a NHS trust hospital (see appendix J). As previously stated, a minor and substantial amendment were submitted and approved by ethics and R&D during the recruitment process. An annual report was also submitted to ethics which informed the committee the study was being written up (see appendix R).

### **2.9.1 Informed consent**

All participants received the patient information sheet with details about the purpose of the study and details of what would be involved. Participants were given the opportunity to ask questions about the study when arranging the interview, the day before the interview and prior to commencing it. Prior to obtaining written consent, I informed participants that every effort would be made to maintain their

anonymity and confidentiality. It was explained that I would be using direct quotes from the interview in the write up but that pseudonyms would be employed. Participants were made aware that the thesis would be submitted to the university to be marked and that the research, or part of it may be published.

Participants were informed of their right to withdraw from the study up to one week after the interview. It was explained that withdrawal after this time could result in their data still being included in the analysis. I also highlighted the reason for the time limit being because if participants withdrew their data, it would impact on the analysis. Additionally, it was explained that even if they chose to withdraw, their data could not be erased, in line with the University research policies. I re-iterated that their participation was voluntary and would not impact on their routine medical care. There was no evidence during this process to suggest that any participants lacked capacity to consent (Mental Capacity Act [MCA], 2007) other than the case previously described [*see section 2.7.1, stage four*].

### **2.9.2 Confidentiality and anonymity**

All participants were assigned a participant number prior to interview and a gender specific pseudonym. The former was used on interview transcripts and the latter was used in the write up. All third party information including names of healthcare professionals, family members, hospital names, wards and locations were omitted. These were noted in the transcript as [wife's name] or [hospital 1].

### **2.9.3 Data storage**

Following the interviews, the data was transferred onto a University computer and then onto an encrypted memory stick, the data was then deleted from the computer. The encrypted memory stick was stored in locked filing cabinets at the University of Nottingham. Identifiable information (consent forms, study summary request

forms, audio recordings and a sheet matching participant name to the pseudonyms and identification number) was stored separately to the non-identifiable information (transcripts and demographic information sheet).

#### **2.9.4 Risk of harm**

It was important to think about potential benefits and risks for the study. Although, adverse events were not expected these were prepared for, given the sensitive nature of the topic under discussion. Therefore, these were clearly outlined in the patient information sheet to help prepare participants.

#### ***Benefits***

The patient information sheet acknowledged that there were no specific benefits for participants other than their account potentially helping inform future practice. However, research suggests that following interviews with CP patients, participants have expressed feeling grateful at having someone listen to their story (Walker, Sofear, & Holloway, 2006). This is important as the literature indicates individuals suffering with CP often feel dismissed by services (Walker, Holloway, & Sofear, 1999). However, I am equally aware that the benefits of having the opportunity to discuss difficulties can vary across cultures (Fuentes, 2004). I recognise that the value of emotional expression in one culture may be in contrast to the value of stoicism in another (Fuentes, 2004).

#### ***Risks***

Given that IPA is an iterative process, the interview schedule only served as a guide. This meant that questions were formulated at the time of the interview depending on the information participants disclosed. Therefore, the depth and detail of information discussed was dependent on participants' answers to the questions. This was detailed in the patient information sheet alongside the potential that

the topic of discussion could evoke distress. Three participants became emotional when discussing how their life had changed due to their neuropathic pain. On these occasions I offered the participants the opportunity to take a break or stop the interview altogether. These participants reported being surprised at their reaction to the interview. I was mindful at these times of my role being that of a researcher, however I felt my clinical skills were useful in helping the participants feel contained and supported.

## **2.10 Analysis**

During the analysis I was interested in learning about my participants' psychological experience and meaning-making of their SCS treatment journey. This involved a cyclical process of moving from description to interpretation, from particular personal examples to more general categorisations of converging and diverging themes, both within and across transcripts (Smith & Osborn, 2008; Smith et al., 2009). During the analysis, I experimented with different ways suggested to organise the data; using post-it notes and word documents until I found a process that suited both me personally and my data. I completed an audit trail to record the interpretation process as it occurred which involved documenting my thoughts at each stage of the analysis (see appendices S-W for an example of the audit trail). I broadly worked within the framework advocated by Smith et al. (2009). This aims to aid novice IPA researchers. However, I attempted to be flexible in my use of these guidelines.

### **2.10.1 Stage One: Transcription**

Following each interview, I transcribed the digital recording. I found this to be an important part of the analytic process as it allowed me to engage closely with participants' accounts and use my notes made in the interview to contextualise their narratives. During this process, I made use of my reflective diary to note any assumptions,

observations or interesting ideas. This way, I could refer back to these at a later stage, when required.

### **2.10.2 Stage two: Initial engagement with the text**

The first stage involved reading and re-reading the first transcript of data. I also listened to the digital recording. This aided my memory on how certain things were said, providing further context to claims and concerns. In addition, I was able to reflect upon richer parts of the data and more challenging parts of the interview for me or the participant. In order to make the participant the focus of this process, I again made notes of any interesting observations to help redirect my attention to the meaning of what the participant was conveying (Smith et al., 2009).

During this active engagement with the data, I paid attention to the shifts from more generic explanations to detailed descriptions given of particular events. This helped me to focus on different parts of the interview in relation to the underlying narrative. This was helpful in moving away from the chronological order of the interview schedule (Smith et al., 2009).

### **2.10.3 Stage three: Exploratory coding**

I completed a close, line by line, analysis of the transcript (Larkin et al., 2006). In order to do this, I created four columns on a page which were titled: Initial themes (for next stage of analysis), line numbers, transcription and exploratory coding. Although there are no specific rules as to how to undertake this, I drew on Smith et al. (2009) guidelines and completed three levels of exploratory coding: Descriptive (Blue), linguistic (red) and conceptual (purple) coding (see appendix T for example of exploratory coding).

### ***Descriptive***

The descriptive comments aimed to describe the content of the account in relation to participants' CNP and SCS surgery. Key words or explanations were noted alongside assumptions and emotional responses, for both participant and analyst (Smith et al., 2009). I aimed to focus on their relationship to the important things that made up their experience of pain and SCS, but very much taking these at face value, as advised by Smith et al. (2009).

### ***Linguistic***

The linguistic comments focus on participants' use of language. At times when the language and content were related, this was noted. For example, I made comments on participants' use of pronouns, as a few participants moved from using 'I' to 'you' within their accounts. Noting these examples allowed me to reflect on what this change may represent. Also, any pauses, laughter, repetition, metaphors and changes in tone and fluency were also noted (Smith et al., 2009).

### ***Conceptual***

Conceptual comments formed the more interpretative, and interrogative aspect of the exploratory coding (Smith et al., 2009). This draws on the descriptive and linguistic comments, to think on a more abstract level about the data. It encouraged me to think about what participants were saying, how they were saying it, and also what they were not saying. I often took an interrogative approach, questioning what certain claims meant to the participants. For example, when Maya repeatedly asserted her need to 'carry on as normal' (said a total of 24 times), I wondered what it would mean to Maya to stop and not carry on as normal? It took time to reflect on this and refine my ideas. It also involved drawing on personal reflections at a micro and macro level. For example, when participants talked about avoidance, I reflected on times that I have avoided certain tasks or thoughts. I also reflected on a broader level

as to how I previously understood SCS and my new developing understanding the experience (Smith et al., 2009).

Examples of this coding were taken to supervision and to a peer review support group, in order to ensure the exploratory coding was sufficiently embedded within the original data.

#### **2.10.4 Stage Four: Developing initial themes**

The aim at this stage was to reduce the volume of the coding, whilst maintaining the complexity of associations within the coding (Smith et al., 2009). This involved fragmenting participant stories and re-organising the data. Thereby, my role became more central during this interpretative process (Smith et al., 2009). The aim was to capture an understanding based on the participants' original account but also my interpretations of this account. This was captured through pithy statements which were noted in the left-hand column of my table (see appendix U for example of initial themes).

I again sought supervision in this process to ensure the audit trail was clear as I moved further into the interpretative process of IPA. Of note, I chose to change the term emergent themes to initial themes, as suggesting that themes emerge from the data could be interpreted as minimising the researcher's role in interpretation (Braun & Clarke, 2006) which is inconsistent with the hermeneutic underpinnings of IPA.

#### **2.10.5 Stage Five: Searching for connections across themes**

Thus far, the themes were in the chronological order of the transcript (Smith et al., 2009). Therefore, I listed the themes in alphabetical order; this allowed me to see similar themes that could be collapsed or removed. Any themes removed were placed into a table of removed themes, alongside a reason why I felt they should not be



included. At this point, I documented how many times a theme had occurred within the transcript. This is referred to as a numeration analysis (Smith et al., 2009). The aim is not to perceive frequency as representing the only indicator of importance but it aided the conceptualisation process of how relevant it was to the participant (Smith et al., 2009; see appendix V).

I then began to think creatively about how the themes may fit together. At this point, I experimented with different ways of doing this. I tried looking at the list and how themes converge and diverge, but also tried using post-it notes to display the themes so I could visually map out the connections. I found the former to be more manageable and appropriate to identify the relationships between the initial themes.

During the process of trying to identify the super-ordinate themes that captured how the initial themes linked together, I employed three techniques: Abstraction, subsumption and polarisation (Smith et al., 2009). Abstraction involves clustering initial themes together that are similar and subsumption is when an initial theme becomes the super-ordinate theme. Lastly, polarisation is where oppositional relationships between themes were captured (Smith et al., 2009). For example, the re-occurring polarisation within the transcripts was the positive and negative aspect of SCS.

During this process, I made a number of entries in my reflective diary, as I wanted to ensure that the interpretation process was sufficiently documented to help me reflect on my decisions to retain or discard themes. This was also aided by the removed themes table. Once I had finished exploring the connections and patterns, I created a table of the super-ordinate themes and relevant initial themes (see appendix W).

### **2.10.6 Stage six: Moving to the next transcript**

The next stage involved moving on to the next transcript and repeating this process. In line with IPA's idiographic commitment, as far as possible, I tried to bracket previous ideas from the other transcripts. However, I also acknowledge that this cannot completely be achieved. I found using my reflective diary helped with remaining true to each individual account. I reflected on times I felt I was being influenced by other transcripts so I could return to these notes later when I brought them together, if relevant.

### **2.10.7 Stage seven: Pattern across transcripts**

I then began to look for the connections between the transcripts. I laid out each table and scanned them for connections and potency which led to some re-labelling of themes. I completed a recurrent theme table as for larger samples; this is suggested to be a useful means to see where themes were applicable to more than half the participants (Smith et al., 2009; see appendix X for recurrent theme table). I sought supervision for a critical voice on my analytic process, to see that my reasoning was clear and embedded in the original data. The analytic process continued as I wrote up the results, where I included a table to represent the whole analysis (see journal paper).

## **2.11 Quality assurance measures**

A number of quality assurance criteria have been developed for qualitative research methods (see Denzin & Lincoln, 2011; Elliott, Fischer, & Rennie, 1999; Yardley, 2000). These criteria aim to ensure the quality and credibility of qualitative research given the subjective nature of these methods. For the current study, I employed a number of strategies aiming to convey trustworthiness (Denzin & Lincoln, 2011). I also followed Yardley's (2000; 2008) criteria of being sensitive to context, showing commitment and rigour, demonstrating transparency and coherence and ensuring the

research has an impact and importance. The ways this was achieved will now be outlined.

### **2.11.1 Study preparation**

During planning the study, I familiarised myself with the SCS treatment process in the hospital undertaking the SCS surgery (Sheldon, 2004). This was to ensure I understood relevant details of the process. This helped me be sensitive to context during the interview so I understood, and could be responsive to, what participants were referring to, and descriptions of any specific SCS events. I also thought about the context within which the interviews would take place. Therefore, I offered participants the option of having them at home or in the hospital environments, which were both familiar places, inherent to their CNP experiences.

### **2.11.2 Audit trail**

An audit trail was kept of all analytical decision making so that there was documentation of the rationale of my choices. In addition to this, during the write up of the study, I provided sufficient details of the procedure and analysis, employing participant quotes to establish an audit trail for the reader. This contributes to the coherence, rigour and trustworthiness of the findings (Denzin & Lincoln, 2011). However, I acknowledge that certain details of changes to the procedure could not be included in the journal paper due to word limitations.

### **2.11.3 Supervision and peer support**

Regular supervision and peer support (IPA peer support group) was sought during different stages of the analysis. This was to increase the credibility and plausibility of my coding and interpretations (Smith et al., 2009), ensuring they were reflective of the original data. Gaining convergence of interpretation was not the aim of this process, as accuracy and objectivity were not the focus. This also

was a useful means to develop my analytical skills throughout the process.

#### **2.11.4 Reflective diary**

The reflective diary was employed to reflect on decision making, challenges during recruitment, the analysis and the final write-up. Initial reflections following the interviews were also digitally recorded (see appendix S). Through noting preconceptions and observations during the analysis, I was able to refer back to these during the write up. These strategies contributed toward demonstrating transparency and coherence (Yardley, 2000, 2008).

#### **2.11.5 Impact and importance**

There are clinical implications that have been identified, which can increase professionals and future SCS candidates understanding of the experience of this procedure. Therefore, it has potential for impact and importance for those in the neurosurgical and pain management fields.

### **2.12 Quality assurance methods not employed**

There were also methods of quality assurance not employed in the current study. The technique and reason for exclusion will now be discussed.

#### **2.12.1 Triangulation**

Triangulation is mixing data methods to gather diverse viewpoints to validate claims being made about data (Olsen, 2004). It is used by those working within a realist framework and can be used to assess 'reliability' of qualitative analysis (Madill et al., 2000). It can also be employed to corroborate researchers' perspectives of the data to strengthen the understanding of the findings (Yardley, 2008). However, this can be perceived as trying to find a 'truth' in participants' accounts or attempting to gain external verification of the

analysis (Ponterotto, 2005). In the current study, I did not aim to find a 'truth', therefore did not need evidence of 'accuracy' or 'objectivity' (Madill et al., 2000, p.3) of the participants' accounts. In line with my critical realist epistemological position, I believe there are multiple perspectives of reality at any given time. It would also be adding another level of interpretation from a different person which is inconsistent with the double hermeneutic central to the IPA process. It was for these reasons I did not employ triangulation in the current study.

### **2.12.2 Participant validation**

Participant validation is another process used to validate qualitative data. This involves clarifying with participants that the information yielded is a true reflection of their account. I did not employ this method as it again is not in with my epistemological position. I recognise the accounts captured are specific to time and context and they are likely to change if I interviewed them at a different time and place. This is reflected by one of my participant's comments at the end of his interview: *'it's been nice to get it out, and in fact I might feel a lot different now I've actually sat down and phuff (noise with mouth) and brought it out'*. Therefore, I did not feel that participant validation would achieve the purpose of validating claims made in the interview. Instead, it would add new reflections to the account, changing the double hermeneutic of that time and context. Furthermore, participant validation makes considerable demands on participants' time (Barbour, 2001) and potentially their physical as well as emotional well-being. This further reinforces it not being appropriate for the current participants who are often in discomfort and pain.

### **2.13 Researcher characteristics**

As part of the reflexive component of qualitative research it is important to identify any personal influences on the research and to convey characteristic about myself. I am a trainee clinical psychologist, who takes an integrative approach to my clinical practice, drawing on a range of psychological theories such as systemic, narrative, cognitive-behavioural, attachment and psychodynamic. All my previous clinical experience has been working in mental health. However, I had recently developed an interest in the area of physical health, which has increased since undertaking this research. I do not have experience of CNP or SCS surgery. Prior to this research, I had not conducted any research employing qualitative methods. This was another novel avenue of exploration. Although I have previously found the structured nature of quantitative research comforting, this is not necessarily consistent with the integrative approach to my clinical practice. Therefore, the flexibility in qualitative methods provided a learning opportunity to broaden my research skills and deviate from more structured thinking.

### 3.0 Extended Results

The following section is an extended version of the themes previously identified in the journal paper. It aims to provide a more comprehensive understanding of participants' experiences, providing more details of the commonalities and divergences between participants.

#### 3.1 Diminished control and coping

This theme reflects coping with the psychological, physical and social impact of CNP alongside the diminished sense of control that occurred at multiple levels as participants worked their way through the system. It draws on the coping processes utilised both before and after SCS surgery.

##### 3.1.1 Battling the system and managing expectations

All participants described a battle through the system, managing expectations, and trying various unsuccessful treatments. However, for some, it was also a battle with the system. During the course of their treatment journey, four participants described not being believed and feeling stereotyped by professionals. These participants did not only have to cope with the impact of their pain, but also others responses to this invisible illness, leading to low mood, hopelessness or anger. Nicole's extract indicates the initial response she received from services at the beginning of her treatment journey:

**Nicole:** *'...went to doctor (hesitation, inhales), which was a bit of waste of time, cos he thought I was just trying to skive off work...I suppose back pain, it's er, a common one'*

For Nicole, she initially experienced this by her doctor, however she continued to experience these reactions years later, in other contexts. Such experiences contextualise the battle for these CNP patients, depicting the numerous challenges presented; it becomes

clear how they can end up in a desperate and hopeless position in trying to cope with the internal experience of pain and external pressures related to CNP. This was particularly depicted by Sally and Sarah in their fight to gain SCS which dominated their interviews. Both participants found themselves in a waiting game, where they felt punished and let down by the system as they struggled to secure funding. Sally's first stimulator had to be removed, however, it had provided four and half months of pain relief, which motivated her to fight for another: *'I really missed that four and half month, and it was that four and half month that thought, yeah, you've got to go and, and fight to get it back'*. For Sally, her attempts to gain control changed as her desperation increased. She went from bargaining, to pleading, to pestering HCPs as illustrated in the following extracts:

**Sally:** *'Just kind of get me the money, the funding to get it done, let me have it done, and I'll walk away and you'll never hear from me again'*

This turned into pleading:

**Sally:** *'I said to them 'look you know, just let me have this one chance, another one chance, it wasn't my fault in the first place it [SCS] had gone wrong, if the machine had of been working perfectly, you wouldn't have had all this trouble'*

This then changes to pestering:

**Sally:** *'I knew at some stage that if I kept pestering and pestering and pestering (laughing) they would either say clear off or yeah we'll give you the money...which obviously succeeded'*

Although the process for Sally and Sarah had happened over the course of years, their experiences appeared quite vivid in their mind



as well as their associated emotions. Although anger was a common emotion amongst participants, some participants presented with an enforced passivity, like a learned helplessness as they struggled with the devastation of returning '*back to square one*' (Mike and Pete). This impacted on participants' expectations of SCS in different ways. Sally and Mike both had a previous SCS removed due to complications. Therefore, they talked about keeping their expectations low, although not all participants were able to do this. For Mike, despite maintaining awareness of his previous disappointments, he continued to describe hope and gratitude for this opportunity:

**Mike:** '*I couldn't wait for it [second SCS], you know, cos I thought, it's surely not gona happen twice and it didn't... I was great, grateful at the chance to have it done again*'

Mike alluded to some worries about gaining another infection with his second implant, but like most other participants he described a faith in SCS. Sadly for Mike, his replacement SCS had recently stopped providing adequate pain relief six months post implant. Mike likened his SCS experience to a rollercoaster:

**Mike:** '*it's been a rollercoaster really, mentally it's been 'oh great, this is gona be good and...this works, be positive er, physically it was good [SCS], but now it's not good, so again, it's a rollercoaster*'.

This rollercoaster meant uncertainty for Mike, or perhaps certainty of needing to accept this was the end of his treatment journey (as presented in the sub-theme disappointment, adaptation and acceptance). However, this metaphor represents well the unpredictable nature of patients' treatment journey, like an emotional rollercoaster.

### 3.1.2 Multiple levels of powerlessness

A sense of powerlessness was experienced on many levels at different points throughout participants' treatment journey. Four participants described particularly negative experiences in hospital, however only three of these were related to their SCS experience. These three participants described feeling dismissed by hospital staff and feeling there was a lack of organisation which negatively impacted on their care. Two participants had difficulties gaining pain relief post-operation. Sarah's treatment journey was saturated with powerlessness, not only in her struggle to secure SCS funding, but also in getting an appointment for the operation and her subsequent time in hospital. As Sarah told her story of problems with her post-operation pain relief, she was sarcastic in tone in the interview, indicative of her underlying anger and disbelief at her treatment. Her desperation for someone to listen was apparent as illustrated in the extract below:

**Sarah:** *'She [nurse] keeps telling me to click the hand [on morphine drip], I say 'I am clicking' she goes 'it's going through', she kept checking the monitor, so I said 'well I'm obviously not getting enough pain relief' I said 'so go and get someone to make sure I'm getting enough pain relief'...she said 'just let me check', she went 'oh dear it's not in your hand' (sniffs). So I hadn't had any pain relief'.*

The demanding demeanour of Sarah's pain identity alluded to here, came across in the interview as she recalled the events. Sarah made reference to an unhealthy dynamic between her and the staff. As her pain increased, her behaviour became more demanding, increasing staff frustration. This led to them being less likely to listen to her concerns and complaints, leaving Sarah feeling not listened to and lacking control. Others described a similar cycle, Nicole felt *'the staff just weren't, weren't interested'* as

she tried to explain she needed the morphine pump as paracetamol just would not do.

This powerlessness was also experienced in relation to medication and SCS side-effects. Four participants reported unpleasant SCS side-effects which heightened their awareness of their movements. The way these side-effects were experienced differed amongst participants, apart from Jack and Maya who both described experiencing intense shocks. This extract highlights not only the powerlessness, but the associated anxiety:

**Jack:** *'you get a little bit paranoid about what you're doing next (pause), if you get what I mean, because you don't want it to do it again. So you-you know sometimes, I feel like I'm sat there like a doll, I don't want to move, because if I scratch that bit, bang I've got it again'.*

The lack of control over the side-effects placed further cognitive demands on these participants, making them more vigilant. In contrast, Nicole and Pete also experienced physical difficulties from the side-effects. Nicole lost her balance and Pete lost the feeling in his leg, which placed him in some dangerous situations:

**Pete:** *'I suddenly lost all feeling in my left leg, and I'm driving, and I ended having to drive for the last (inhales) 5 or 6 miles...literally picking my leg up and pushing it down on the clutch to change gear and lifting it back up again and that's how I, that's the only way I got home'.*

Participants described adapting to this powerlessness and consequently feeling ambivalent about their SCS. This links with disappointment, adaptation and acceptance sub-theme.

### 3.1.3. Coping with symptoms of depression

All but one participant explicitly talked about coping with symptoms of depression however, the remaining participant Maya, presented as emotional throughout the interview. Maya did not explicitly report feeling down; rather, repeatedly talked about needing to 'carry on as normal'. This seemed to be a coping mechanism, a way of avoiding her sadness, pain and losses. Becoming emotional in the interview was not isolated to Maya; two other participants were surprised by their tearful reaction to telling their stories. The content of their accounts indicated transitional emotions, but also this underlying more long standing low mood and/or negative thinking, which was evident in other accounts.

The depressive symptoms varied amongst participants, however all described low mood such as feeling 'miserable', 'very low', 'at a low eb' or 'depressed'. Additionally, participants explicitly described or alluded to cognitive and behavioural symptoms of depression, such as negative or ruminative thinking or loss of motivation. Sally and Pete spoke specifically of a cycle of depression reporting losing motivation to attend to self care and appearance due to not going out or seeing anyone, as illustrated below:

**Sally:** *'...just downright miserable.... I thought, oh why bother, you're not going out, you're not doing anything, erm, and that did carry on right through the time, erm, I binged on a hell a lot of weight, I didn't particularly care, I wasn't bothered, and just kind of let myself go'.*

Similarly, Pete described previously falling into a downward depressive spiral due to having to give up his career. This resulted in loss of identities and friends, thereby overlapping with the identity loss and impact on pain sub-themes:

**Pete:** *'you lose all your dignity...you've not got a job, you've got er all you friends who you had in the job were in, don't want to know you, because their working, you've got nothing to do, nobody wants to go out with you, because, you know they've got other things to do, you lose all your friends, you lose all contact with everybody else and as I say, you get into this mind-set that, erm, why should I bother? I'm not going anywhere today, I've got nobody to see and so, you end up not having a shave...you just sit about all day'*

Pete alludes to experiencing learned helplessness; he no longer had control over many aspects of his life, leading to loss of motivation to self care. It is a critical period for Pete during the interview, as his SCS had not met his expectations. This, coupled with potentially having to give up work led Pete to think about how he would cope with his motivation loss and lack of change in his pain relief. Pete and Mike were in many ways in a similar position due to their SCS not currently working for them and having the knowledge *'there's nothing else, if this doesn't work'* (Mike). Both described a similar way of active coping, through bringing meaningful activities to each day. As Mike described:

**Mike:** *'I could lay down all day, no one here would moan [family]...but there's no way mentally I want to do that, so as long I can do one thing a day, whether it's one drawing or (inhales), something, erm I feel quite happy, if I can do one thing a day, then lay down...I erm (pause), like to do something, er, otherwise you waste your life away laying in bed and I don't like that'.*

It seemed Pete, went from employing more passive, avoidant coping strategies to more active strategies (e.g. meaningful activities), having learnt from previous experience. Shifting between the two forms of coping was evident in all accounts. This theme inter-relates with other themes, particularly the SCS disappointment, adaptation

and acceptance sub-theme. Coping with such symptoms have been an ongoing process for all but one participant. In contrast, Sally's low mood dissipated following SCS with her speaking only of happiness and positive change since her implant.

#### **3.1.4. Impact of pain and the non-able body**

This theme encompasses the profound impact participants' CNP had on them psychologically, socially and financially, as well as the impact it had on those close to them. This feeling of being physically restricted seemed to be at the core to all other difficulties, as highlighted by Sarah:

**Sarah:** *'you can handle the pain to a certain extent, but not being able to do is the (pause), is the killer really'.*

Three participants explicitly described an on ongoing conflict between what they wanted to do and what they were physically capable of doing. It seemed these participants had compartmentalised their lived experience in line with a dualistic view of a separate mind and body *'Your mind wants to do things, but your body can't do things'* (Nicole). This was the source of much frustration, which can be likened to the aging process where the body can slow down faster than the mind. There is a sense that participants were aging prematurely as indicated by others responses to them *'I'm not young, but I don't want to be treated like an old man'* (Mike). Therefore, trying to cope with this appeared to focus around trying to get on with things and adapting their lifestyle accordingly. In contrast, Maya reported knowingly pushing herself too far and suffering as a result.

Additionally, participants reported being aware of the impact their condition had on others. Five participants described how their restrictions had negatively impacted on their relationships; this

included relationships with partners or/and families. For Sally, she felt her reluctance to go out, due to her tired body, put a strain on her relationship:

**Sally:** *'it did put strain on things...he'd say you know, shall we go out, shall we go here, or whatever, and I'd say well no I feel tired and I want to go to bed, I can't'.*

Whereas for Maya, it was more related to physically not being capable:

**Maya:** *'...you want to keep up with everybody else and, you know you want to do things with your kids and have fun un, you know, do what they want you to do, and join in, but knowing you're not capable of it, I think it spoils it'.*

This inability to keep up with others and join in, often led to participants to feeling or actually being excluded from social events with family and friends. For Jack, he describes his experience as being in an observer role, an outsider looking in but unable to be a part of it:

**Jack:** *'you sit in the side lines all of the time and it's a really horrible feeling, it really is, cos you feel like, you, even though they-they don't make me feel like that, but you feel like you're at the edge of your family all the time, you can never get into the middle of it'*

This physical barrier appears to induce a mental partition where participants felt separated from the world around them. This was echoed in three other accounts, where they felt excluded by not being able to drink alcohol and join in. These negative effects of medication were not restricted to participants' social life; a total of five participants described various unpleasant medication side-effects.

Nicole and Pete reported their medication impacted on their cognitive abilities. For Nicole, her reduction in concentration negatively impacted on her ability to do her job, isolating her from work colleagues who she felt did not understand her pain. Participants appeared to generally not feel themselves on medication. This concept of presenting with a medicated self was captured by Jack in his account about the impact of his excessive sleeping:

**Jack:** *'if I took some [medication] of that in morning, I use to sleep until 5/6 o'clock in-in the evening...Then I use to be awake in a little bit, bit dopey for a couple of hours...It'd be time to have some more, sleep all night, and then, so I didn't get to see the kids really. It upset the kids because obviously I-I wasn't me, if you know what mean (pause)...it was like everything seemed slowed down if you know what I mean, when people were talking to me and everything, and I think that frightened the kids slightly cos it was like, what you being like this for?'*

This demonstrates the impact of his medication on his family life and how his children were unable to understand how he was when medicated. The sense of guilt associated with this left Jack in an awkward position, of being in pain or scaring his children, hence his preference for his SCS.

All participants described the different ways they coped with these changes. They reported becoming dependent on their medication or others or on physical aids. They also made various lifestyle modifications; behaviourally, environmentally and cognitively as a means to prevent pain. Behaviourally, participants avoided certain movements, whereas environmentally they adapted their homes (e.g. banister on stairs) or at work got ergonomic chairs or supports to accommodate their pain. Three participants talked about cognitive adaptations in relation to having to plan everything they did. They



described or alluded to loss of spontaneity and freedom due to having to think about their capabilities, as illustrated by Pete in the extract below:

**Pete:** *‘Now I have to think, I’m going there, what do I do when I get there? How am I going to get about?... You have plan everything you do, otherwise you’re gona end up in a lot of pain’.*

Such adaptations were not restricted to prior to the SCS surgery as demonstrated by Maya:

**Maya:** *‘...It doesn’t matter what you do in life, in your everyday life, you have to (pause) consider, am I capable of doing that?...But you’ve got to consider, I’ve got to take all of my pills with me, I’ve got to take my, you know, my stimulator with me [remote], and everything, it’s like, it’s like a baggage’.*

Such measures act as an additional pressure and constant reminder to participants of their restrictions and changes they have had to make for their pain. Participants also described adapting to living with the stimulator which is described later. The most pronounced impact for this group of participants seemed to be on the relational aspects of their identities, which is captured in the next theme.

### **3.2 Identity transitions**

All participants talked about experiencing loss of meaningful aspects of their lives, particularly significant roles, thereby fragmenting their sense of self and impacting negatively on their self-esteem and mood. An additional part of the process is self-acceptance of this new aspect of themselves; their pain identity.

### 3.2.1 Identity loss

This theme depicts the loss of the social self and subsequent group identities. Common to all participants, was this loss of belonging to a group whether this be related to friendship groups, family, work, group sports or activities. All participants referred to their past active, functional selves, often detailing the sports and activities they previously were involved in. There was a sense of associated grief in not being able to do them anymore. For Nicole, her life was full of different activities where she led teams in competitions, providing her with purpose, friendship groups and a sense of achievement:

**Nicole:** *'I use to do an awful lot of sub-aqua diving, cos I'm an advance diver, cross country orienting, fair walking...I got involved in, a lot with the dogs with doing erm, agility courses...But that's all running around and that's out the window now'.*

And later she describes how she gradually lost such roles and consequent group identities:

**Nicole:** *'I was with, a very active group of people aannd initially it was ok, a little bit of time and you end up back up with them and then you turn, you end up with a stick and then crutches, and as things gets worse and then you are just not wanted because you're an embarrassment'.*

The meaning she once gained from the group was lost as her pain identity and associated disability became more established. This loss of her active role in this friendship group in conjunction with feeling rejected by those she valued appeared to reduce her feelings of self worth. This led to a learned helplessness with Nicole giving up on feeling angry about their perceptions and accepting it: *'You give up having feelings (pauses, eyes filling up), you just learn to accept it (cries)'.*

The sense of belonging yielded from these group identities was prevalent in relation to work roles as well. The four participants who were no longer working talked about the loss of their work roles and the implications of this. Common to most was again this sense of having a purpose and the social aspects of working. Sally described her job as a hair dresser as all she wanted to do but had to give up due to the standing involved. When talking about why she missed her job, she explained:

**Sally:** *'...I suppose the going out, the meeting people, erm (pause), and feeling as though you are doing something in your life'*

Similarly, Jack commented:

**Jack:** *'it's like going to work, when you, cos obviously you get relationships at work as well, friends and stuff, you miss out on all that'*

Jack also alluded to feeling he was not fulfilling his role as a husband in providing for his family *'I feel like I should be supporting me family'*, which was an emasculating experience alongside being dependent on his wife to shower and dress him. In contrast, for Sarah not being able to work meant she could not fund social activities, therefore lost these social roles.

For the three participants who continued to work, they had to adapt their roles to accommodate their pain, which for Pete and Maya induced a sense of loss. For Pete, his career was an enormous part of his current and future identity, a disruption that had been difficult to accept, resulting in depressed mood as previously described. This is illustrated in the following quote where he describes the impact of having to change work roles which was a loss of a role he valued:

**Pete:** *'I'd got my (cough), my career planned out, that this is the route I'm gona take and this is where I'm going to go, but, that suddenly came to a halt...you go down in that spiral, your life's ruined'*

And later...

**Pete:** *'it rips your heart out, you know, this is the job, this is the vocation you've set your heart on and somebody's taken it away (hesitation) and (pause) it, you lose, you lose all your dignity, because you know, you've got nothing now, you've not got a job, you've got er all you friends who you had in the job were in, don't want to know you, because they're working, you've got nothing to do'.*

There was a sense of mourning the loss of their roles and few references to developing new ones. It seemed that SCS had great significance to these role and identity losses as the outcome of the SCS surgery for many participants would determine whether any could be re-claimed or adapted. This links with the disappointment, adaptation and acceptance sub-theme which captures this acceptance process of losses that did not change and the pain identity.

### **3.2.2. Managing the unwanted pain identity**

Five participants referred to their pain identity in a predominantly negative manner due to perceiving these aspects of themselves as particularly undesirable and shameful, such as being 'bad-tempered', 'aggressive', 'unresponsive', 'short-tempered' and having 'no patience'. Maya talked explicitly about her embarrassment of being someone with a disability and her attempts to avoid this label.

**Maya:** *'I had to use the stick for a while and I wouldn't go out the house, I would never go out the house and use the stick cos I felt embarrassed...*

*..R (Researcher): What would you say that you felt embarrassed about?*

*I (Interviewee): Feeling hu-, that I had a disability and it was affecting me, erm (sniffs, pause) but I try not to think about it'*

For Maya, it was not only the label that was upsetting; it was how it affected her and her ability to cope with it. In order to dispel the negative emotions associated with attending to this part of her, she avoids thinking about it. Thinking about this, perhaps meant accepting this aspect of herself, which she was finding hard to do. Since her SCS she described learning her limits and seemed to be trying to accept her capabilities. There was a contradiction in Maya's account suggesting she was in some kind of identity transition. She struggled with the visibility of her disability and being treated differently by others, yet she equally yearned for validation of the distress that it brought her:

**Maya:** *'it's more because people look at me and think there is nothing wrong with me, and then they don't know...what's within do they so? They don't know what you've been through...I think sometimes I can't come to terms with that [disability label], even you know this far on, this far down the line (sniffs), that still bothers me, that I'm classed as having a disability now'.*

This heightened awareness of how their pain and disability were visible was evident in five other accounts. Exactly how it was visible was unique to each participant, for example physical aids (e.g. walking stick), body language (e.g. behaviours in response to pain such as hobbling), or mood. Participants appeared to feel that others defined them by their pain so they masked the visibility of their

disability and associated emotions or avoided situations. Mike and Jack also explicitly talked about not wanting to be treated differently and how the visibility of this aspect of their identity conflicted with this wish. For Mike, the stimulator had given him hope that a reduction in his pain behaviours would inadvertently impact on others responses to him. He talked about finding it frustrating being put into a sick role and being treated differently to others:

**Mike:** *'...looking forward to being without, hobbling about and people sort of, asking how I was, cos I get fed of, I hate sympathy (laughs, hesitation)...they all mean very well, but er, I hate it, being sort of fussed over... I don't want to be treated like an old man...I'm not a macho man, by any means, but I-I hate being fussed over'*.

The latter part of this description suggests others' response to the visibility of his pain, were emasculating, a threat to his sense of self which perhaps was already threatened by his pain identity. Therefore, Mike used humour as a coping mechanism and hope, hope that SCS would *'bring him back to normality'*. Similarly, Maya repetitively expressed her desire to be normal, which for Maya was being her pre-pain self. This desire for *'normality'* was referred to in all accounts. However, for some participants the meaning of normality adapted over time. For Jack, when his pain was significantly reduced by the SCS, it was a traumatic experience due to experiencing a sense of loss. His experience of pain had become his normality, part of him. This again centralises pain as shaping participants' experience and sense of self, representing a conflict for Jack between his unwanted pain identity and what had been a consistent experience for 20 years:

**Jack:** *'I don't know why I was so upset about it not hurting, I think it was more because it should have been, I'm that use to it being that way, it was quite upsetting because I thought there was something*

*wrong because it wasn't hurting, but it wasn't, it was cause something was right and it wasn't hurting, which after a while, it was brilliant'.*

### **3.3 SCS Conflict**

This sub-theme captures what the SCS surgery outcome meant to the participants. Most participants were ambivalent about SCS and were weighing up the positive and negative aspects of it. In contrast, one participant felt solely positive about its effects, another felt a conflict between feeling grateful for his stimulator but disappointed in the lack of change.

#### **3.3.1 Positive change**

This encompassed the positive impact the pain relief had on six participants. Interestingly, four participants used the same phrase to describe the pain relief they gained, reporting it 'takes the edge off it' which had a positive impact on their mood. In contrast, Nicole experienced greater benefits from her stimulator as illustrated in this extract where she compares her current pain relief to the past:

**Nicole:** *'it's getting on for a eight years now from when it all started, so you're talking about, six months ago, so seven and a half years with not been out of pain, to the pain being reduced by something like 90%'*

In addition to pain relief, four participants reported being able to do more. However, the level of change differed amongst participants. Most described numerous smaller changes that had a significant impact on some aspect of the participant's life. For example, for Mike being able to sit for longer periods meant a lot to him on a social level as he did not like exhibiting pain behaviours, nor being treated differently:

**Mike:** *'I could sit and eat a meal, without having to get up half way through it, I could sit on an ordinary chair....when I use to visit friends, I could sit there a while without having lay down'*

Similarly, being able to stand for longer had made Nicole's working life easier. In contrast, the changes for Sally were profound resulting in significant changes in her lifestyle and in her sense of self.

**Sally:** *'going about more, and do more things.... just the total image of me, has totally changed, because I'm caring more about myself now, because I feel more confident, I feel more happier'*

Being in less pain, meant Sally was happier, going out more and taking care of her appearance. She became less self-focused and was able to attend to her husband and parents more which appeared to increase her sense of self worth. Sally, Sarah and Jack remarked that others had commented on the change in their appearance and mood which was a validating experience for them. A couple of participants made reference to having hope about future roles. However, for most it was more about recognising the importance of having roles to help cope with their symptoms of depression. For Sally, she had started to look and plan ahead:

**Sally:** *'I'd like to get back to work'*

However, it appeared that in order to be able to consider re-establishing identities, participants needed to have reached some level of acceptance of their situation. The amount of change achieved by the SCS seemed to dictate where participants were in this acceptance process.



### 3.3.2 Disappointment, adaptation and acceptance

This theme encompasses participants' feelings about their stimulator post-operation. It demonstrates that SCS meant far more than a form of pain relief to these participants. It represented hope for change in various aspects of their lives. This sub-theme captures the ways in which expectations were not met and associated disappointment, adaptation to the device and acceptance of the extent of change experienced.

For three participants their disappointment was in contrast to their gratitude for the stimulator, which for Sarah evoked a sense of guilt.

**Sarah:** *'I shouldn't be disappointed in any of it...Cos it's took the pain away'*

Sarah felt given the stimulator had reduced her pain; she should be content, but she was not, demonstrating her higher expectations. In contrast, Pete denied feeling disappointed about his SCS. However, he alluded to disappointment when describing how his SCS had not met his expectations gained from the trial and how he was unprepared for the side-effects. There was a sense Pete feared negative evaluation for describing his dissatisfaction, as illustrated in the extract below:

**Pete:** *'I'm starting to sound ungrateful, I'm not ungrateful, I'm grateful to everything everybody's has done, I appreciate this operation's probably cost a lot of money to the tax payer and everybody's tried their hardest...But (pause) I'm no different now than I was in 2002...which I thought I would be...'*

Although Pete felt there was no change, he still used the stimulator and was adapting to living with it like the other participants. Pete, alongside four other participants, particularly described adapting to

having the battery inside. A predominant concern was the visibility of the battery, as Nicole asserts:

**Nicole:** *'it does stick out, whereas, I, my idea of an implant was it would go in and you wouldn't notice it.'*

Due to this internal battery being felt externally, most participants described catching it on clothing and experiencing discomfort in certain positions, particularly whilst sleeping. Consequently, it was more cognitively demanding than anticipated. Some participants talked about adapting to changing their settings on their SCS. For Jack, he changed his setting depending on whether he was walking or sitting so it would give different levels of stimulation that were comfortable and suited to the task:

**Jack:** *'So it's quite hard to remember, if I'm sitting and I've got it on the sit one [setting], if I want to stand up and go and pick a cup up, I've got to turn it off a second, sit back down turn it back on'*

Maya also described the time and consideration required to operate the stimulator:

**Maya:** *'you have to set that up (pointing to stimulator) to accommodate what you are doing for the day...You know, if you're doing a lot of stretching, you have to lower it, you know, I've had it, tweaked a few times, you know, but, cos you get like different stimulations...there's a lot of consideration'*

This was not the only way the stimulator preoccupied Maya's and Jack's attention, as they also talked more in-depth about this idea of having a 'foreign body' inside, which for Jack evoked paranoia and catastrophic thinking:

**Jack:** *'...the-the thought of having like unnatural things inside you is scary anyway. It's like It's probably literally impossible for it to do, but you think what would happen if the battery leaks'.*

I wandered at this point, whether this statement was a form of reassurance seeking. Unlike most participants, Jack experienced excessive worry about his stimulator which left him with mixed feelings about his stimulator. In summary, this shows the various ways participants were adapting to and accommodating their stimulator.

Another predominant process in all accounts was acceptance of no change or the level of change achieved. Following Mike's SCS not working, he contemplated possible causes for this change and oscillated between hope and a forced acceptance:

**Mike:** *'I'm just hoping that it's a phase, erm, like it's not working now, but maybe, erm it will pick up and it will work... I'm sort of clutching at straws now, but erm, you know, and maybe there is another operation... or this is it, if I've gotta learn to live with it, I'll have to learn to live with it, make the most of it'*

Mike, like all other participants, had previously referred to SCS as being his last treatment option but when faced with the prospect of his SCS not working, it was difficult to embark on this process of acceptance. Although, other participants' stimulators had successfully provided pain relief (excluding Pete), they were also making this transition to accepting the level of pain relief and capabilities, which for most participants meant accepting the loss of certain activities and their old selves:

**Nicole:** *'I'm realistic, I won't be doing the things I was use to be doing'*

Similarly...

**Sarah:** *'So regardless of the operation [SCS], erm, things are not gona change to what they were before'*

Despite an improvement in Jack's sense of self, he still felt like he could not move forward:

**Jack:** *'I'm literally just stuck in a rut now, you know, and I think it's a case, you've just got to make the best of what, what you've got at the time I think. You know, because I know for a fact there isn't gona be a miracle cure'*

This idea of being 'stuck in a rut' is suggestive of a mundane lifestyle that cannot be changed. It portrays a sense of being trapped, a need to resign himself to his situation, or even accept it.

### **3.4 Summary**

All participants were caught up in this conflict of SCS, either through a positive or negative experience of SCS or both. The outcome of SCS, adaptations and acceptance processes were indicative of a number of simultaneous transitions underway. For Sally, she was moving forward, establishing new identities, however most participants were accepting losses and adapting to life with their SCS.

## **4.0 Extended Discussion**

The current study aimed to explore CNP patients' experiences of the SCS surgery treatment journey, considering life prior to, and after the surgery. It would not have been possible to understand participants' experiences of SCS without consideration to their journey leading up to the surgery. The themes generated from the analysis will be discussed in relation to the wider CP and SCS surgery literature alongside clinical implications, study limitations and suggestions for future research.

### **4.1 Diminished control and coping**

The first theme illustrates how participants experienced a sense of powerlessness as they simultaneously coped with the devastating impact of pain, whilst managing hopes and disappointments associated with battling the system to gain treatments and eventually SCS. This will be discussed in relation to existing literature.

#### **4.1.1 Battling the system and managing expectations**

All participants described experimenting with different treatments, however some participants also experienced not being believed and stereotyped by healthcare professionals (HCPs) during this process. These findings are consistent with research indicating CP patients experience both felt and enacted stigma from HCPs and wider society (Newton, Southall, Raphael, Ashford, & LeMarchand, 2010; Snelgrove & Liossi, 2009). Such discrimination is often in response to there being no obvious physical cause for the pain, or as a result of patients not responding to pain treatments (Holloway, Sofaer-Bennett, & Walker, 2007). These types of responses from others can have a detrimental impact on patients' feelings about themselves and hope for rehabilitation. Conversely, it is also suggested that repetitive treatment failures and associated distress can trigger CP patients anger towards HCPs (Morley, 2008) resulting in difficult relations between patients and services.

During this treatment journey, two participants in the current study spoke at length about their struggle with services in securing SCS. These findings provide novel insights into patients' experiences of barriers to gaining a SCS. Existing research has focused on assessment criteria and patient suitability (e.g. Celestin, Edwards, & Jamison, 2010; Doleys, 2006; Sparkes, Raphael, Duarte, LeMarchand, Jackson, & Ashford, 2010) as opposed to the experience of going through the process. In the current research, the barrier to funding resulted in distress and anger. The research into finances related to SCS focuses on the cost-effectiveness of SCS (see Manca et al., 2010; Simpson, Duenas, Holmes, Papaioannou, & Chilcott, 2009; Turner et al., 2004). However, given that SCS for CNP was recently recommended by the National Institute of Health and Clinical Excellence (NICE, 2008) and The British Pain Society (BPS, 2009), there is likely to be an increase in funding for suitable patients over the next few years. Therefore, difficulties in this process should be explored and addressed and the emotional well-being of the patient in this process should be paramount. As previously identified (see journal paper) patients may be at a critical point in their treatment journey, having had numerous failed treatments. Therefore, delays and difficulties could be disempowering, disappointing and result in further low mood, frustration and a consequent increase in pain. Further qualitative research is required to build on these initial insights of the experience of the SCS assessment process and how patients get SCS.

Another important aspect of this journey for current participants was their experience of having past expectations of treatments and current expectations of SCS. Research suggests that SCS expectations can impact on treatment satisfaction (Doleys, 2006), which was apparent in the current study. The influence of expectations can be demonstrated by an RCT whereby patients assigned to the SCS and physical therapy treatment reported

significant pain reduction, even before the stimulator had been implanted (Kemler et al., 2000). Doleys (2006) highlights how patient satisfaction is likely to depend on whether expectations have been fulfilled, but also patients' perceptions of the effort of medical practitioners involved. Some participants in the current study talked about being informed SCS is not a cure, but culturally there is often the expectation that doctors and surgeons will eliminate disease demonstrating the need for a change in perspective with SCS (Beltrutti et al., 2004). In practice, it is important that expectations and goals are explicitly identified (e.g. how much further a patient wants to walk, how much pain relief they expect, activities they want to improve, Van Dorsten, 2006). It is also recommended that practitioners maintain an awareness of their expectations (Doleys, 2006) as these are likely to influence how patients perceive SCS.

#### **4.1.2 Multiple levels of powerlessness**

Throughout the treatment journey participants described multiple ways in which they experienced feelings of powerlessness. This was experienced whilst battling the system to gain treatments including SCS, but also in hospital when having the SCS implanted. Some participants reported feeling dismissed by HCPs when trying to ascertain pain relief post-surgery. Research indicates that some nurses report finding it hard to cast aside their own judgements of patients' pain (Richards & Hubbert, 2007). It suggests stereotypes of pain patients may influence nurses understanding of patients' presenting behaviour when pressured on the ward, as opposed to considering the way they are acting in the context of them being in pain. Lack of understanding of the impact of pain on patients emotionally and behaviourally could contribute to negative interactions between patients and HCPs. Therefore, this warrants further research.

Participants also felt powerless to SCS side-effects (e.g. losing balance, loss of feeling in a limb and unpredictable shocks). This experience of SCS side-effects is documented in the literature (e.g. Kemler et al., 2004). However, the current study is the first to provide initial insights on patients' perspectives of these experiences. Kemler et al. (2004) reported that all SCS patients who still had an implant at two years follow-up reported side-effects. The two most prevalent side-effects were change in amplitude of stimulation by bodily movements in 19 out of 22 participants, and paresthesia (numbing/tingling of the skin) in other body parts in 13 out of 22 participants (Kemler et al., 2004). Despite providing quantitative data, there was no qualitative information to inform how patients coped with, or adjusted to these experiences. In the wider literature, qualitative studies on Implantable Cardioverter Defibrillators (ICDs), have provided insights into the impact of perceived control and adjusting to this implant (Deacon, Dunbar, Moloney, Sears, & Ujhelyi, 2003; Hallas, Burke, White, & Connelly, 2009; Morken, Severinsson, & Karlsen, 2009). The function of this device is different to SCS, as it regulates the patient's heart beat by issuing a shock. However, the perceived lack of control over unpredictable shocks associated anxiety, catastrophic thinking and depression due to the experience of lack of control (Goodman & Hess, 1999; Hallas et al., 2009) echoes some accounts in the current study. Further research is required on the impact of SCS side-effects on psychological well-being, as well as the adjustment to SCS in order to build on the current study's initial insights. This information could inform psycho-education during pre-surgery preparation and also post-surgery support during the adaptation process.

#### **4.1.3 Coping with symptoms of depression**

Throughout the treatment journey, both pre and post SCS, participants described coping with depressive symptoms. The reciprocal relationship between CP and depression is well



established (Beltrutti et al., 2004). Research suggests that a person's beliefs about the meaning of their symptoms, their ability to control their pain and the impact it has on their life play a central role in CP (Turk & Okifuji, 2002), which is also associated with depressive symptoms (Richardson et al., 2009). This reinforces the importance of understanding patients' beliefs and how in control they feel of the pain and their stimulator, as this can impact on patient pain perception and subsequent mood, which is discussed later [see section 4.3.1 and 4.3.2].

The way that participants coped with depressive symptoms is intrinsically linked to coping with the impact of their pain. Literature provides different ways to conceptualise coping with chronic pain and depression such as active or passive (avoidance) coping (see Snow-Tyrek, Norris, & Tan, 1996) or assimilative or accommodative coping (Schmitz, Saile, & Nilges, 1996). The current participants showed evidence of assimilative coping (e.g. active attempts at seeking treatments) and accommodative coping (e.g. accommodating pain by changing their goals). The latter of which is associated with preventing depressive symptoms (Schmitz et al., 1996). However, participants in the current study appeared to fluctuate between these modes of coping depending on life events as opposed to adapting a specific coping style. Potentially now participants have the SCS, they may reduce their assimilative strategies related to seeking treatments due to SCS being the last option for most. This is supported by participants reporting changing their goals (e.g. doing one meaningful thing a day) and learning the limits of their capabilities, which indicates the initial stages of a process of acceptance and potentially accommodation to their new pain levels and capabilities which could eventually impact on their mood. [see section 4.3.2. for further discussion of adaptation and acceptance post-SCS surgery].

#### **4.1.4 Impact of pain and the non-able body**

Participants detailed various ways their CP had negatively impacted on their lives, particularly the physical restrictions, activity limitations and subsequent social losses. The influence of pain on CP patients quality of life (QoL) is extensively documented (e.g. Miles, Curran, Pearce, & Allan, 2005; Morley, 2008; Snelgrove & Liossi, 2009). The impact of pain was present both prior to, and following SCS surgery. However, specific changes post-SCS will be addressed in the SCS conflict theme.

A key finding in the current study was the discrepancy between participants' desire to do things and their physical capabilities. This is consistent with research indicating the painful body as central to everything and preventing spontaneous engagement with the environment (Bullington, 2009; Miles et al., 2005; Smith & Osborn, 2007; Snelgrove & Liossi, 2009). This experience is described as a disruption in the 'mind-body-world' experience which prevents those suffering with CP from 'being-in-the-world' (Bullington, 2009, p. 107). CP patients' attention is focused on their painful body resulting in their bodies becoming the 'object of action' as opposed to a means that facilitates action (Miles et al., 2005, p. 438). Leder (1990) emphasises how our attention to our bodies is generally absent, but that pain becomes a 'force that stands opposed to the self' (Leder, 1990, p. 4), thereby creating this mind and body divide depicted in the current findings. Such a divide is perceived as a central target of rehabilitation to help patients see their physical body as more than just a source of pain that restricts them and that they are more than a person in pain (Bullington, 2009). Although, pain may not be eliminated, individuals with CP can be helped to interact more with their environment (Bullington, 2009). This can be achieved through various treatments such as behavioural strategies which focus on reducing the threat posed by pain, by reducing avoidance of certain activities and gradually increasing engagement with activities (Belrutti

et al., 2004). Increasing engagement in activities could reduce the influence of lack of social engagement that was reported by participants in the current study. Such strategies may be an important adjunct treatment to SCS when adapting to their capabilities post-surgery. *[see section 4.4.3 for further discussion]*.

## **4.2 Identity transitions**

The second theme illustrates how participants have experienced multiple identity losses as well as learning to cope with their unwanted pain identity.

### **4.2.1 Identity loss**

Participants experienced loss of their social roles and group identities and made few references to developing new ones. Similarly, literature indicates CP patients experience role loss, and subsequent attribute loss, as opposed to identity development (Harris et al., 2003). Harris et al. (2003) perceived roles as external expressions of a person's social interaction, and attributes were defined as 'internalised cognitive representations of the self in relation to others' (p. 363). The authors suggested roles consist of certain attributes; some attributes could be retained by their presence in multiple roles. However for some, the loss of a role meant the loss of a set of attributes. In the current study, the loss of attributes and the sense of purpose associated with roles within group activities (e.g. leadership roles) altered participants' sense of who they were due to them perhaps defining aspects of themselves through their belonging to the group. This was associated with symptoms of depression which was supported by Harris et al. (2003) who found that such role losses were associated with depression even when other factors known to contribute were controlled.

This concept of losing aspects of the social self is extensively referred to in the CP literature (Hellström, 2001; Miles et al., 2005;

Smith & Osborn, 2007). The social self in the present study included work roles, where participants either had to adapt/change work roles due to their pain or were not able to work. Occupation is an important way in which people express and define themselves (Henare, 2003), and also provides another social arena for engagement with others. Therefore, there was a void or sense of emptiness for those not working in the current study. There was also a sense of mourning past, pre-pain active selves, which is consistent with literature suggesting CP patients often make comparisons to their pre-pain selves (Hellström, 2001; Smith & Osborn, 2007); particularly, the threat of not being able to do things or not being able to do them to the same proficiency challenges peoples' identity (Miles et al., 2005). There was a sense of idealisation and nostalgia of the strong and active former self (Hellström, 2001) which made it more difficult for participants in the current study to embrace their new pain identity. Holding onto lost identities is seen as counterproductive due to it preventing people from adapting to their new situation (Hellström, 2001). Therefore, being able to integrate their pain identity into how they see themselves is an important part of rehabilitation (Smith & Osborn, 2007). Psychological treatments could assist in facilitating this process for SCS patients as it may impede the benefits yielded from their stimulator.

#### **4.2.2 Managing the unwanted pain identity**

Literature suggests CP patients feel more conscious of their pain and disability in the social domain due to the fear of judgement by others (Smith & Osborn, 2007). This was prevalent in the current study with participants being acutely aware of the visibility of their disability and how this impacted on others perceptions and reactions to them. The associated shame led participants to mask their pain and associated behaviours. Gustafsson, Ekholm and Ohman (2004) suggested that moving on from shame to self respect, by reducing the divide between the self and the body can facilitate rehabilitation.

Therapeutic interventions for targeting identity have been suggested to be important for CP patients especially in cases where sensory modulation has not been successful and patients are trying to live with their pain (Morley 2008). However, I would argue such interventions would still be useful for patients gaining successful sensory modulation from devices such as SCS. Even though the stimulator provides pain relief, this study indicates SCS patients still struggle with the same identity challenges as they learn to accept their pain and capability levels as is depicted in the next theme.

### **4.3 SCS conflict**

The final theme illustrates how most participants were experiencing conflict in relation to experiencing both positive and negative aspects of the stimulator. All but one participant alluded to going through a process of acceptance of their post-SCS pain relief and capabilities alongside adjusting to living with the stimulator.

#### **4.3.1 Positive change**

Comparable with existing literature, participants in the current study reported SCS reduced their pain and improved their mood (Jamison et al., 2008; Kumar et al., 2008; North & Shipley, 2007). It also indicates that previous physical challenges and restrictions improved for some participants as a result of their SCS (e.g. sitting longer, standing longer). This is consistent with existing literature suggesting improvements in quality of life, particularly improving functional status are sought prior to SCS (Anderson et al., 2001) and improved following SCS (Kumar et al., 2008). For one participant, her SCS experience had a profound positive impact on her confidence, sense of self, social life and optimism about the future. This offers new insights into the positive impact of SCS, as there is no other literature providing such detail. This highlights the importance of more qualitative research being undertaken in this area to gather further insights about what SCS means to patients post-surgery.

### 4.3.2 Disappointment, adaptation and acceptance

In contrast to the above, most participants also alluded to feeling disappointed about some aspects of their stimulator, often due to it not meeting certain expectations as previously discussed. In previous SCS research, structured questions have been asked to ascertain patient satisfaction (e.g. 'are you satisfied with the pain relief provided by your treatment?' and 'based on your experience so far, would you have agreed to this treatment?' Kumar et al., 2007, p.181). In contrast to the current findings, this RCT (n=100) found 33 out of 50 participants in the SCS treatment group reported being satisfied with their pain relief (66%), and 43 out of 50 participants felt they would have agreed with the treatment knowing the outcome (86%; Kumar et al., 2007, p. 185). Participants in the current study are likely to have responded positively to the above questions as all but one reported being happy with their pain relief and some explicitly commented that they did not regret their SCS decision (e.g. *'I am pleased I've got it and I don't think I would turn back the clock of saying no I don't want it'* – Maya). However, such measures of satisfaction fail to capture the ambivalence and difficulties in adapting to the SCS which was also discussed in the current study. This highlights the importance of further research into patient satisfaction with SCS using multiple methods of evaluation which give patients the opportunity to expand on their SCS experiences.

Participants in the current study described adapting to the presence of the stimulator and living with it. Participants reported discomfort from the positioning of the battery, side-effects and adapting to changing the settings. They specifically emphasised the cognitive demands of the stimulator. These findings provide novel insights into SCS adjustment. Previous research has yielded information through questionnaires post-SCS or quantification of interview data, restricting the depth of information gained. These cognitive demands of the stimulator are an important consideration. Pain can be seen as

an interruptive signal, an alert for threat, however when chronic and unable to control this interruption, if perceived as threatening, it can increase distress and depression (Linton et al., 2011). Therefore, depending on how the cognitive demands of the stimulator are perceived, this could also have a negative impact on patients' mood. In the current study, there were a couple of participants who talked more extensively about associated paranoia and anxieties related to certain aspects of the stimulator. Therefore, further research is warranted to explore patients' perceptions of their stimulator, as it could potentially act as an additional interference to daily activities having a negative impact on mood which will inevitably impact on the SCS efficacy. It is such cognitive and behavioural adaptation that may warrant evaluation post-SCS to increase SCS adjustment. An American article on psychological considerations for implantable procedures draws on the SCS and wider surgical literature to consider post-surgical support (Van Dorsten, 2006). It emphasises the role of the psychologist both pre and post-SCS, advocating behavioural strategies be employed to gradually increase activity levels with the new level of pain. It also recommends relaxation, stress management and sleep hygiene strategies all to aid the adaptation process to SCS (Van Dorsten, 2006). This article is consistent with the current research in the suggestion that some SCS patients may require cognitive or behavioural post-surgical support whilst adjusting to their stimulator. This may be particularly relevant for those patients whose expectations were not met. In many ways, the current research brings together the CP and SCS literature providing further multidisciplinary insights that could improve SCS efficacy. Although, SCS side-effects were discussed in relation to the feelings of powerlessness in the extended paper, this demonstrates the inter-related nature of the themes, as they were also an important part of adjusting to the stimulator as previously discussed.

Lastly, six participants described the process of accepting their level of pain relief and capabilities post-SCS. This was significant to this group of participants as most had been informed SCS was their last treatment option, placing a lot of pressure on the success of SCS. For these participants the restrictions and subsequent losses were most important to them. Arguably if participants are not able to accept their activity and capability levels post-SCS, this could have a negative impact on individuals' mood. Given that mood can alter a person's pain perception this could result in a perceived decrease in pain relief, which may account of the reduction of SCS pain relief over time that is described in the SCS literature (Ohmeiss & Raubaum, 2001). Therefore, the current study indicates CP patients using SCSs may need to go through a process of adaptation to SCS and acceptance of their level of functioning and pain identity (Smith & Osborn, 2007) prior to re-establishing or forging new identities and engaging in new activities. This process is likely to be different for each individual depending on what their pain means to them, how it impacts on their life and the adaptation to the SCS. As Nicole reflected: *'it's too early to say really how much of an impact it's-it's going to make [SCS], the reduction in pain i-is the big one, all the (hesitation) emotional, psychological things that go with it, they're probably going to take longer'* (four months post SCS). This again highlights the importance of post-SCS support, particularly evaluating how well patients are adapting psychologically as well as practically to their SCS. The aim should be to mitigate interference in functioning and encouraging identity and pain acceptance (Morley, 2008). For some patients, they may benefit from an adjunct psychological treatment during the acceptance and adaption process. It is argued in the literature that both cognitive behavioural therapy (CBT) and acceptance and commitment therapy (ACT) are effective psychological interventions in managing CP (Wetherell, Afari, Rutledge, Sorrell, Stoddard, & Petkus, 2011). They take two quite different approaches with CBT being perceived as a form of



controlling pain through modifying physical sensations, catastrophic thinking and unhelpful behaviours (e.g. avoidance), whereas ACT focuses on accepting pain. In a recent RCT, both treatments were effective in reducing pain interference, depression, pain-related anxiety, but ACT was seen as a more satisfactory treatment to patients (Wetherell et al., 2011). ACT seems more relevant to the current research findings where the focus has changed from previously trying to control their pain, which they now have through SCS, to now accepting their pain and capability levels. Also, the effects of CBT on patients' level of disability due to their CP are reported to be limited (Eccleston et al., 2009), whereas ACT is associated with better functioning (McCracken & Eccleston, 2005), which seemed a primary concern for current participants. Therefore, ACT may be an appropriate psychological intervention that could assist patients struggling during the acceptance and adaptation process post-SCS. Interestingly, two decades ago, practitioners were expressing the view that psychological treatment should be considered post-SCS to address the psychological factors related to pain (Daniel, Long, Hutcherson, & Hunter, 1985). Therefore, perhaps what is of most interest is the factors preventing research being translated into practice.

#### **4.4 Clinical implications**

The current study illustrates the significance of attending to process alongside SCS assessment and outcomes. Given the potential challenges in obtaining SCS, when such issues arise patients should be offered additional support during this critical period in their treatment journey. Psychological assessment and goal setting in relation to expectations may prevent unrealistic goals and could improve treatment satisfaction.

The current study also demonstrates that despite some improvements in mood and activities of daily living, patients were

adapting to their levels of pain relief and capabilities as well as the stimulator. Post-surgery psychological evaluation/monitoring could assist in identifying any unmet expectations, beliefs about the presence of the stimulator, adjustments to living with the device, assistance in increasing activity levels, all of which could help in increasing mood and acceptance of any changes in identities. Support in accepting their pain, and changes or lack of changes, could potentially help patients start to forge new identities and engage with their environment to improve their sense of self and mood.

#### **4.5 Study limitations**

The study inclusion criteria specified recruitment of participants 2-8 months post-SCS surgery. This was to ensure that the interview was close enough to the surgery for participants to recall their life prior to SCS and life post-operation. However, given that the effects of SCS can reduce over time often at approximately 12 months (Cameron, 2004; Ohnmeiss & Rashbaum, 2001; Taylor, Van Buyten, Buchser, 2006), the current results may be restricted to the short-term impact of SCS. However, one participant in the sample had experienced such effects, but at 6 months. Despite this, widening the sample to include patients 12 months post-SCS surgery would have reduced the sample homogeneity. Also, the current study yielded a wealth of information, so it would be more beneficial to complete a separate piece of research investigating SCS post 12 months to capture the necessary depth of information.

Furthermore, when developing the interview schedule I was aware that my interpretation of what constitutes a treatment journey may be different to those I interviewed, so I wanted to keep the questions as open as possible. I was mindful that I did not want the schedule to solely focus on the practicalities of the treatment journey, as the purpose of IPA is to capture the psychological experience, in terms of

the connection between their embodied experience, how this is talked about and made sense of, and the emotional responses to this experience (Smith, 2011). This is why I chose to ask about any changes in terms of how they thought or felt about themselves since their pain onset and life after the surgery. However, in hindsight, it is important to deliberate whether asking about change directly may have led participants to feel they needed to talk about change even if this was not present or important to them. However, the findings indicate participants were able to say when they felt nothing had changed, for example Pete explicitly stated 'my life is no different to before the surgery'. Also, the 'SCS conflict' theme captured participants views of aspects of their lives that had, or had not changed as much as expected. This indicates the lack of change was important to them and this was expressed.

#### **4.6 Future research**

In light of this being the first qualitative piece of research on SCS, it would be useful for further qualitative studies to explore particular parts of the treatment journey in more depth. Future research is warranted on the assessment process for patients, how they experience the selection process, the panel where they present their case for SCS and whether they feel supported in their decision making. Also further qualitative studies on patients' perceptions of the stimulator post-surgery and experience of adjusting to living with the stimulator would help to delineate any further support required in this process as suggested by the current study.

This study highlights the wealth of information on patient satisfaction with SCS that has not been captured by current evaluation methods. Therefore, future research would benefit from broadening the evaluation measures, using interviews or open-ended questions in questionnaires to gain more comprehensive feedback. It would also be useful to survey how frequently multidisciplinary working,

specifically the use of psychological support, is offered, required and employed post-SCS in the United Kingdom (UK).

Lastly, there appears to be a discrepancy between what takes place in clinical practice and the recommendations in the evidence-base/SCS guidelines (e.g. BPS, 2009; European Federation of International Association for the Study of Pain [IASP] Chapters, Gybels et al., 1998; NICE, 2008). This is supported by a survey indicating only 61% of UK pain management centres employed psychological assessment in their SCS selection process (Ackroyd, Bush, Graves, McVey, & Horton, 2005). As previously suggested there is no such data on post-SCS evaluation. It would be useful to build on this research to understand why this is not taking place, identifying any challenges or barriers to implementing such recommendations and the risks of not doing so. Potentially, unsuitable candidates may be selected skewing beliefs about SCS efficacy.

#### **4.7. Conclusion**

The lack of qualitative, in-depth exploration of the treatment journey of SCS formed the rationale for the current research. It has demonstrated the importance of using qualitative methods to gain further insights of patients' experiences of SCS to inform existing quantitative research. The current study has highlighted the lack of understanding of patients' beliefs about SCS, patients' perspectives on the assessment process and adjusting to living with the device in existing literature. This research offers insights into these processes and questions if psychological assessment and evaluation could aid the assessment process and help with identifying individuals who require additional support in accepting their levels of pain relief and capabilities and adjusting to the SCS. This can inform future research in SCS, with the hope of continuing to combine the SCS and CP literature to convey a holistic understanding of the SCS experience. It

is hoped that the insights about SCS expectations and post-SCS surgery conflicts will increase neurosurgical and pain management teams' understanding of the potential challenges for SCS patients during assessment and when adapting to living with the stimulator. This could encourage these teams to draw on psychological therapies, when appropriate, as an adjunct to SCS. On a broader scale, it is hoped that more qualitative studies will be completed to continue to build on these findings and to deepen the understanding of what it means to have SCS surgery from those who matter, the patients.

## **5.0 Critical Appraisal**

In this section, I aim to summarise my research journey, conveying my reflections of the different stages in the research process. Within this, I will refer to scientific, ethical and theoretical issues.

### **5.1 Planning**

The research stemmed from a neurosurgeon who had an interest in the psychological experience of SCS surgery. SCS was novel to me, however I soon became engrossed in the extensive evidence-base for this surgical procedure. This process in itself was particularly challenging due to trying to learn the medical terminology, whilst simultaneously trying to identify what had already been completed and what needed to be explored. I was struck by the lack of qualitative research in the area or any research related to patient satisfaction that was not in the form of a questionnaire. Throughout this process I liaised closely with the neurosurgeon who assisted in my learning experience of medical concepts. Once I had formulated my research objectives, it was important to explain to the team why I had chosen a qualitative project as well as the value of this approach, in what was, a very quantitative field. However, when I presented my research proposal, they seemed positive about something different being undertaken.

During the planning, I took time to learn about the process patients went through, to truly grasp their treatment journeys. I attended multidisciplinary meetings regarding patient selection and obtained documentation employed in the assessment process to gain an understanding of the patient journey. During this process I was surprised by the lack of psychological assessment in the service as it is advocated in SCS guidelines, but the neurosurgeon assured me referrals were made for those where psychological concerns were highlighted in the SCS screening process.

## **5.2 Recruitment process**

The recruitment process was challenging for both practical and ethical reasons. The participant pool ended up being smaller than first predicted. Therefore I had to amend my inclusion criteria to increase my participant pool. *[see section 2.7.1 for details of difficulties recruiting participants]*. Re-applying to ethics and the trust was a stressful process however one that I came to learn was a reality of conducting research in the National Health Service. During the recruitment process, there was some confusion about the recruitment protocol within the research team so it was important to regularly communicate and reiterate the protocol. However, this again presented me with the reality of working in a multidisciplinary research team with busy clinicians whose priority, unlike mine, was not my research. It highlighted the importance of me being proactive in communicating information in different formats to make sure all team members were aware of protocols and rationale for decision making.

In addition to this, during recruitment a patient contacted me regarding the study. However, he reported being physically unwell at the time following the removal of his SCS due to complications. During the conversations, it appeared his central motivation for participating was his experience of the difficulties in recruiting for research. Although there were practical difficulties as well, my priority was my ethical commitment to the patient. I considered his capacity to consent in line with the MCA (2007) during this period of disappointment and felt the interview may not be appropriate at this time. Supervision was also helpful during this process. *[see section 2.7.1, stage four for further details]*.

## **5.3 Interviews**

I found conducting the interviews enlightening, but equally challenging as I was not there in my capacity as a clinician, I was

there as a researcher, yet was required to provide support to emotional participants. Although, it was initially a strange experience, I soon was able to support participants in my researcher role, helping them feel contained by allowing them time to stop the interview when required and letting them know it was ok to feel emotional given the sensitive information being discussed. During this process I think I truly came to understand what phenomenologists mean when they talk about empathically entering and reflecting on the participant's lived world (Wertz, 2005). Following interviews, I found myself lost in thought and reflections about what it would be like to live in their world, with so many restrictions, having gone from normal life to losing so much, to then adapting to a machine inside of them. What would it mean to me to not be able to walk for long periods, not be able to go to the gym, to go out spontaneously? How would this make me feel about myself? I was saddened even by thought of this, as alluded to in my reflective diary:

'Having had this interaction, I can't help but reflect on my life, it makes me think about the bigger picture of what I have. I have a bigger picture beyond this experience, yet that sense making of his experience, his painful existence, that was it, raw in front of me, where was his bigger picture? Did he have a bigger picture than pain? It seemed all consuming.'

During the course of my second interview, as the interpretative process began, I became aware of preconceptions I never realised I had. A process alluded to by Gadamer (1990) whereby only in the process of interpretation do you truly start to see the influences of your thoughts. I felt surprised at the sheer disappointment I was sensing from this participant. I realised, perhaps I had been more influenced than I thought by the surgeon's positivity about SCS,



despite my awareness of the mixed results in the literature. I was thankful to learn this early as it was useful to be mindful of in future interviews. Additionally, I previously had concerns that participants may hold back information, knowing the neurosurgeon who completed their surgery was involved in the research. Conversely, I felt that participants felt relieved they'd had the opportunity to talk about their experiences and seemed eager to provide feedback to help future SCS patients. This was evident in the way that some participants spoke out, as if they were talking to potential SCS patients *'I think people just got be, not too hopeful'* (Sally).

#### **5.4 Analysis**

The analysis was mentally and physically exhilarating and exhausting. I found myself oscillating between the concern of being too descriptive or too interpretative. I recalled an article I had read where Gee (2011), had highlighted the importance of remembering that as long as the interpretations were grounded in the data, that in-depth interpretations actually elucidate IPA's objective to see 'the things themselves'. This encouraged me to have faith in my instinct. Generating new insights was anxiety provoking as it re-organised the chronological flow of the narratives into a new form, however it was equally exciting and motivating. An experience I had never had from quantitative research.

On a personal level, this was in contrast from my usual structured way of working. This, in many ways, was a personal challenge. It encouraged me to increase the flexibility of my thinking and sit with the uncertainty that qualitative analysis can evoke. Such uncertainty was particularly prominent when I was working across the transcripts. Despite some obvious commonalities between my data, I was overwhelmed by the amount of diversity. During times when finding commonality is difficult, Smith, Flowers and Larkin (2009) encourage researchers to think on a higher level to find the shared experience.

After much thought and reflection I began to see more subtle similarities than I originally thought. I reframed my feeling about this and felt confident I had achieved the shared higher order quality, whilst showing within the theme the participants' unique idiosyncratic experience. I came to understand the balance of convergence and divergence as being a sign of good IPA (Smith, 2011).

## **5.5 Writing up**

My research journal paper is for submission to a neurosurgery journal. Therefore, I felt it was important to reflect on my rationale for this choice and my experience of developing a qualitative piece of work for a medical journal.

Given the dearth of research on the psychological experience of SCS surgery, I felt my target audience needed to be the surgical and pain management teams who work with these patients. I felt submitting to a neurosurgery journal would ensure the insights from my research were communicated to those who would benefit from it. I originally wanted to submit to a neuromodulation journal which would target predominantly neurosurgeons undertaking these procedures such as SCS<sup>7</sup>. However, it was difficult to communicate the depth of the treatment journey in the restrictive word limit. This, I felt was a significant point as it highlights a potential obstacle of submitting IPA studies to non-psychological journals which can be the most crucial audience. I also feel, as clinical psychologists, we should strive to communicate and disseminate psychological information to other professionals. This is why I chose to change to the Journal of Neurosurgery as it targeted a similar audience but also allowed for the depth due to a more accommodating word count. This way I could ensure the relevant information was conveyed.

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<sup>7</sup> Neuromodulation is a pain control technique where pain relief is achieved by modulating noxious messages, changing their activity without making permanent lesion in neural tissues (Beltrutti et al., 2004). It can be achieved through chemical or electrical methods (Beltrutti et al., 2004).

During the write up, it was difficult to know when to stop analysing. I was aware that the write up was a key part of the analytical process but it was difficult making decisions about what to include in the journal paper to concisely answer the research question. Here lay a key conflict for me; I was trying to balance my commitment to IPA, alongside my intended audience who are dominated by the medical discourse. During this process, I found myself being aware of my use of language, specific terminology that is often employed during IPA analysis was not necessarily appropriate for the intended audience. I felt that by aligning with one, I was betraying the other. After much deliberation, I feel I managed to balance this appropriately so that the phenomenological and hermeneutic underpinnings were adequately conveyed but not at the expense of its accessibility. This example from my reflective diary illustrates my sense making of this experience:

‘So I find myself questioning whether the neurosurgeons reading this really want to hear about the exhausting burden of the non-able body that creates a rupture between the patient’s body and world restricting their abilities to create new selves. Or do they simply want to hear that patients experienced activity limitations and physical restrictions which influenced how patients felt about themselves, how do I find the balance?’

As previously mentioned, it took time to explain qualitative research to the SCS team. This reinforced the importance of how I conveyed the information in my article making sure I emphasised that the data was not meant to be generalised or objective in nature.

## **5.6 Multi-disciplinary team working**

In light of my journal article encouraging more multi-disciplinary working between neurosurgeons and the wider pain management teams and my systemic interests, I felt it was important to reflect on my experience of working in a multidisciplinary research team with individuals from multiple systems. Given the technical language in the literature, it was helpful having a neurosurgeon in the research team. I found his description of concepts more accessible than reading about them in books. It helped me to be able to integrate a psychological perspective into the understanding of these concepts and also how to assert them in an accessible manner to others. It was also important to stay focused on what I was required to know for the purpose of the project rather than getting too distracted by the wider surgical literature which was not necessarily relevant. Significantly, I have also learnt to appreciate the difficulty in balancing research commitments with clinical demands, something I shall remember for the future.

## 5.0 References

- Ackroyd, R., Bush, D. J., Graves, J., Mc Vey, J., & Horton, S. (2005). Survey of assessment criteria prior to implantation of spinal cord stimulators in United Kingdom pain management centres. *European Journal of Pain*, 9, 57-60.
- Anderson, V. C., Carlson, C., & Shatin, D. (2001). Outcomes of spinal cord stimulation: Patient validation. *Neuromodulation: Technology at the Neural Interface*, 4(1), 11-17.
- Backonja, M. (2003). Defining neuropathic pain. *Anesthesia and Analgesia*, 97, 785-790.
- Barbour, R. S. (2001). Education and debate. *British Medical Journal*, 322, 1115-1117.
- Beltrutti, D., Lamberto, A., Barlet, G., Bruehl, S. P., Doleys, D., Krames, E., et al.,... Melzack, R. (2004). The psychological assessment of candidates for spinal cord stimulation for chronic pain management. *Pain Practice*, 4(3), 204-221.
- Biggerstaff, D. F., & Thompson, A, R. (2008). Interpretative phenomenological analysis (IPA): A qualitative methodology of choice in healthcare research, *Qualitative Research in Psychology*, 5, 173-183.
- Bouhassira, D., Lantéri-Minet, M., Attal, N., Laurent, B., & Touboul, C. (2008). Prevalence of chronic pain with neuropathic characteristics in the general population. *Pain*, 136, 380–387.
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3(2), 77-101.

- Breivik, H., Collett, B., Ventafridda, V., Cohen, R., & Gallacher, D. (2006). Survey of chronic pain in Europe: Prevalence, impact on daily life, and treatment. *European Journal of Pain*, 10(4), 287-333.
- Brew, B. J. (2003). The peripheral nerve complications of human immunodeficiency virus (HIV) infection. *Muscle & Nerve*, 28(5), 542-552.
- Brocki, J. M., & Wearden, A. J. (2006). A critical evaluation of the use of interpretative phenomenological analysis (IPA) in health psychology, *Psychology and Health*, 21(1), 87-108.
- Brook, A. L., Georgy, B. A., & Olan, W. J. (2009). Spinal cord stimulation: A basic approach. *Techniques in Vascular and Interventional Radiology*, 12(1), 64-70.
- Bullington, J. (2009). Embodiment and chronic pain: Implications for rehabilitation practice. *Health Care Analysis*, 17(2), 100-109.
- Cameron, T. (2004). Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: A 20-year literature review. *Journal of Neurosurgery*, 100(3), 254-267.
- Carter, S. M., & Little, M. (2007). Justifying knowledge, justifying method, taking action: Epistemologies, methodologies, and methods in qualitative research. *Qualitative Health Research*, 17(10), 1316-1328.
- Celestin, J., Edwards, R. R., & Jamison, R. N. (2009). Pretreatment psychosocial variables as predictors of outcomes following lumbar surgery and spinal cord stimulation: A systematic review and literature synthesis. *Pain Medicine*, 10(4), 639-653.

- Charmaz, K. (2008). Grounded Theory. In J. Smith (Ed.), *Qualitative Psychology: A Practical Guide to Research Methods*. (2<sup>nd</sup> ed., pp. 81-110). London: Sage.
- Clarke, K. A., & Iphofen, R. (2005). Believing the patient with chronic pain: A review of the literature. *British Journal of Nursing*, 14(9), 490-493.
- Closs, S. J., Staples, V., Reid, I., Bennett, M. I., & Briggs, M. (2007). Managing the symptoms of neuropathic pain: An exploration of patients' experiences. *Journal of Pain and Symptom Management*, 34(4), 422-433.
- Closs, S. J., Staples, V., Reid, I., Bennett, M. I., & Briggs, M. (2009). The impact of neuropathic pain on relationships. *Journal of Advanced Nursing*, 65(2), 402-411.
- Crowe, M., Whitehead, L., Gagan, M, J., Baxter, G, D., Pankhurst, A., & Valledor, V. (2010). Listening to the body and talking to myself – the impact of chronic lower back pain: A qualitative study. *International Journal of Nursing Studies*, 47(5), 586–592.
- Daniel, M. S., Long, C., Hutcherson, W. L., & Hunter, S. (1985). Psychological factors and outcome of electrode implantation for chronic pain. *Neurosurgery*, 17, 773-777.
- Deacon, C., Dunbar, S. B., Moloney, M., Sears, S. F., & Ujhelyi, M. R. (2003). Patient experiences with atrial fibrillation and treatment with implantable atrial defibrillation therapy. *Heart and Lung*, 32(5), 291-299.

- Deer, T. R. (2010). Complications of spinal cord stimulation. In T. R. Deer. (Ed.), *Atlas of implantable therapies for pain management* (pp. 43-51). West Virginia, USA: Springer.
- Denzin, N. K., & Lincoln, Y. S. (2011). *The SAGE handbook of qualitative research*. (4<sup>th</sup> ed.). London: Sage.
- Department of Health. (2005). *Creating a patient-led NHS: Delivering the NHS Improvements Plan*. London: Department of Health.
- Devulder, J., De Laat, M., Bastelaere, M., & Rolly, G. (1997). Spinal cord stimulation: A valuable treatment for chronic failed back surgery patients. *Journal of Pain and Symptom Management*, 13(5), 296-301.
- Doleys, D. (2006). Psychological factors in spinal cord stimulation therapy: brief review and discussion. *Neurosurgery Focus*, 21(6), 1-6.
- Dworkin, R. H., Backonja, M., Rowbotham, M. C., Allen, R. R., Argoff, C. R., Bennett, G. J et al.,...Weinstein, S. M. (2003). Advances in neuropathic pain: diagnosis, mechanisms, and treatment recommendations. *Archives of Neurology*, 60, 1524-1534.
- Eatough, V., & Smith, J. A. (2008). Interpretative phenomenological analysis. In C. Willig & W. Stainton-Rogers (Eds.), *The sage handbook of qualitative research in psychology* (pp. 179-194). London: Sage.
- Eccleston, C. (2001). Role of psychology in pain management. *British Journal of Anaesthesia*, 87(1), 144-152.



- Eccleston, C. (2011). A normal psychology of chronic pain. *The Psychologist*, 24(6), 422-425.
- Eccleston, C., Williams, A. C., & Morley, S. (2009). *Psychological therapies for the management of chronic pain (excluding headache) in adults*. The Cochrane Collaboration: John Wiley & Sons, Ltd.
- Eccleston, C., Williams, A. C., & Stainton-Rogers, W. (1997). Patients' and professionals' understandings of the causes of chronic pain: Blame, responsibility and identity protection. *Social Science and Medicine*, 45(5), 699-709.
- Elliott, R., Fischer, C. T., & Rennie, D. L. (1999). Evolving guidelines for publication of qualitative research studies in psychology and related fields. *British Journal of Clinical Psychology*, 38, 215-229.
- Fade, S. (2004). Using interpretative phenomenological analysis for public health nutrition and dietetic research: A practical guide. *Proceedings of the Nutrition Society*, 63, 647-653.
- Falowski, S., Celii, A., & Sharan, A. (2008). Spinal Cord stimulation: An update. *Neurotherapeutics: The Journal of the American Society for Experimental NeuroTherapeutics*, 5(1), 86-99.
- Flowers, P., Krussen, C., & Duncan, B. (2001). Re-appraising HIV testing among Scottish gay men: The impact of new HIV treatments. *Journal of Health Psychology*, 6, 665-678.

- Fuentes, L. A. (2004). Ethics in violence against women research: The sensitive, the dangerous, and the overlooked. *Ethics and Behavior*, 14, 141-174.
- Gadamer, H. (1990/1960). *Truth and Method* (2<sup>nd</sup> rev.ed.). New York: Crossroad.
- Gee, P. (2011). 'Approach and sensibility': A personal reflection on analysis and writing using Interpretative Phenomenological Analysis. *Qualitative Methods in Psychology Bulletin*, 11, 822.
- Gilron, I., Watson, C. P., Cahill, C. M., & Moulin, D. E. (2006). Neuropathic pain: a practical guide for the clinician. *Canadian Medical Association Journal*, 175(3), 265-275.
- Giorgi, A., & Giorgi, B. (2008). *Phenomenology*. In J. Smith (Ed.), *Qualitative Psychology: A Practical Guide to Research Methods* (2<sup>nd</sup> ed., pp. 26-52). London: Sage.
- Goodman, M., & Hess, B. (1999). Could implantable cardioverter defibrillators provide a human model supporting the learned helplessness theory of depression? *General Hospital Psychiatry*, 21(5), 382-385.
- Guba, E. G., & Lincoln, Y. S. (1994). Competing paradigms in qualitative research. In N. K. Denzin & Y. S. Lincoln (Eds.), *Handbook of qualitative research* (pp. 105-117). London: Sage.

- Gustafsson, M., Ekholm, J., & Öhman, A. (2004). From shame to respect: Musculoskeletal pain patients' experience of a rehabilitation programme, a qualitative study. *Journal of Rehabilitation Medicine*, 36, 97–103.
- Gybels, J., Erdine, S., Maeyaert, S., Meyerson, J., Winkel Müller, B., Augustinsson, L. et al.,...Van Buyten, J. P. (1998). Neuromodulation of pain: A consensus statement prepared in Brussels 16–18 January 1998 by the following task force of the European Federation of IASP Chapters (EFIC). *European Journal of Pain*, 2(3), 203-209.
- Hallas, C. N., Burke, J. L., White, D. G., & Connelly, D. T. (2010). Pre-ICD illness beliefs affect post implant perceptions of control and patient quality of life. *Pacing and Clinical Electrophysiology*, 33(3), 256-265.
- Harris, S. B., Morley, S., & Barton, S. B. (2003). Role loss and emotional adjustment in chronic pain. *Pain*, 105, 363-370.
- Hayes, S.C. (1993). Analytic goals and varieties of scientific contextualism. In S.C. Hayes, L.J. Hayes, H.W. Reese & T.R. Sarbin. (Eds.), *Varieties of scientific contextualism* (pp. 11-27). Reno, Nevada: Context Press.
- Hayes, S. C., & Duckworth, M. P. (2005). Acceptance and commitment therapy and traditional cognitive behavior therapy approaches to pain. *Cognitive and Behavioral Practice* 13, 185-187.
- Hayes, S. C., Jacobson, N. S., Follette, V. M., & Dougher, M. J. (1994). *Acceptance and change: Content and context in psychotherapy*. Reno, Nevada: Context Press.

- Healy, M., & Perry, C. (2000). Comprehensive criteria to judge validity and reliability of qualitative research within the realism paradigm. *Qualitative Market Research An International Journal*, 3(3), 118-126.
- Heidegger, M. (1999). *Ontology - The hermeneutics of facticity*. (John van Buren, Trans). Bloomington: Indiana University Press.
- Hellström, C. (2001). Temporal dimensions of the self-concept: Entrapped and possible selves in chronic pain. *Psychology & Health*, 16(1), 111–124.
- Henare, D. (2003). Frances Rutherford Lecture: “It just isn’t me anymore” Moving forward to new identity. *New Zealand Journal of Occupational Therapy*, 50(1), 4-10.
- Holloway, I., Sofaer-Bennett, B., & Walker, J. (2007). The stigmatisation of people with chronic pain back. *Disability and Rehabilitation*, 29(18), 1456-1464.
- Holloway, I., & Wheeler, S. (2010). *Qualitative research in nursing and healthcare*. (3<sup>rd</sup> ed.). Oxford: Blackwell.
- Husserl, E. (1913/1982). *Ideas: A general introduction to pure phenomenology* (W.R. Boyce Gibson, Trans.). London, UK: Allen & Unwin.
- Jamison, R. N., Washington, T. A., Fancillo, G. J., Ross, E. L., McHugo, G. J., & Baird, J. C. (2008). Do implantable devices improve mood? Comparisons of chronic pain patients with or without an implantable device. *Neuromodulation: Technology at the Neural Interface*, 11(4), 260-266.

- Jensen, T. S. (2002). Anticonvulsants in neuropathic pain: rationale and clinical evidence. *European Journal of Pain*, 6, 61-68.
- Jensen, T.S., Gottrup, H., Sindrup, S.H., & Bach, F.W. (2001). The Clinical picture of neuropathic pain. *European Journal of Pharmacology*, 429, 1–11.
- Kemler, M. A., Barendse, G. A., van Kleef, M., de Vet, H. C., Rijks, C. P., Furnée, C. A., . . . van den Wilderberg, M. D. (2000). Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. *New England Journal of Medicine*, 343(9), 618-624.
- Kemler, M. A., de Vet, H. C., Barendse, G. A., van den Wildenberg, F. A., & Van Kleef, M. (2004). The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. *Annals of Neurology*, 55(1), 13-18.
- Kemler, M. A., de Vet, H. C., Barendse, G. A., van den Wildenberg, F. A., & van Kleef, M. (2008). Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial. *Journal of Neurosurgery*, 108(2), 292-298.
- Kind, P. (1996). The EuroQoL instrument: an index of health-related quality of life. In B. Spilker (Ed.), *Quality of life and pharmacoeconomics in clinical trials* (2<sup>nd</sup> ed., 191-201). Philadelphia: Lippincott-Raven Publishers.
- Krauss, S. E. (2005). Research paradigms and meaning making: A primer. *The Qualitative Report*, 10(4), 758-770.

- Kumar, K., Rizvi, S., & Bishop-Bnurs. S. (2011). Spinal cord stimulation is effective management of complex regional pain syndrome I: Fact or fiction. *Neurosurgery*, 69(3), 566-578.
- Kumar, K., Taylor. R. S., Jacques, L., Eldabe, S., Meglio, M., Molet, J., . . .North, R. B. (2007). Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain*, 132(1-2), 179-188.
- Kumar, K., Taylor. R. S., Jacques, L., Eldabe, S., Meglio, M., Molet, J., . . .North, R. B. (2008). The effects of spinal cord stimulation in neuropathic pain are sustained: A 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation, *Pain*, 63(4), 762-770.
- Kvale, S. (1983). The qualitative research interview: A phenomenological and a hermeneutical mode of understanding. *Journal of Phenomenological Psychology*, 14, 171-196.
- Larkin, M., Watts, S., & Clifton, E. (2006). Giving voice and making sense in interpretative phenomenological analysis. *Qualitative Research in Psychology*, 3, 102-120.
- Leder, D. (1990). *The absent body*. Chicago: University of Chicago Press.
- Leeuw, M., Goossens, M., Linton, S., Crombez, G., Boersma, K., & Vlaeyen, J. (2007). The fear-avoidance model of musculoskeletal pain: Current state of scientific evidence. *Journal of Behavioural Medicine*, 30, 77-94.

- Linton, S. J., Nicholas, M. K., MacDonald, S., Boersma, K., Bergborn, S., Maher, C., & Refshauge, K. (2011). The role of depression and catastrophizing in musculoskeletal pain. *European Journal of Pain*, 15(4), 416-422.
- Madill, A., Jordan, A., & Shirley, C. (2000). Objectivity and reliability in qualitative analysis: realist, contextualist and radical constructionist epistemologies. *British journal of psychology*, 91, 1-20.
- Manca, A., Eldabe, S., Buchser, E., Kumar, K., & Taylor, R. S. (2010). Relationship between health-related quality of life, pain, and functional disability in neuropathic pain patients with failed back surgery syndrome. *Value in Health*, 13(1), 95-102.
- Manca, A., Kumar, K., Taylor, R. S., Jacques, L., Eldabe, S., Meglio, M.,...Sculpher, M. J. (2008). Quality of life, resource consumption and costs of spinal cord stimulation versus conventional medical management in neuropathic pain patients with failed back surgery syndrome (PROCESS trial). *European Journal of Pain*, 12(8), 1047-1058.
- Max, M. B. (2002). Clarifying the definition of neuropathic pain. *Pain*, 96(3), 406–7.
- McCarberg, B., & Billington, R. (2006). Consequences of neuropathic pain:  
Quality-of-life issues and associated costs. *American Journal of Managed Care*, 12, S263-S268.
- McCracken, L. M. (1997). “Attention” to pain in persons with chronic pain: A behavioral approach. *Behavior Therapy*, 28(2), 271-284.

- McCracken, L. M., & Eccleston, C. (2003). Coping or Acceptance: What to do about chronic pain? *Pain*, 105, 197-204.
- McCracken, L. M., & Eccleston, C. (2005). A prospective study of acceptance of pain and patient functioning with chronic pain. *Pain*, 118(1-2), 164-169.
- McCracken, L. M., & Turk, D. C. (2002). Behavioral and cognitive-behavioral treatment for chronic pain: Outcome, predictors of outcome, and treatment process. *Spine*, 27(22), 2564-2573.
- McCracken, L. M., Vowles, K. E., & Gauntlett-Gilbert, J. (2007). A prospective investigation of acceptance and control-oriented coping with chronic pain. *Journal of Behavioral Medicine*, 30, 339-349.
- McDermott, A. M., Toelle, T. R., Rowbotham, D. J., Schaefer, C. P., & Dukes, E. M. (2007). The burden of neuropathic pain: The results of a cross-sectional survey. *European Journal of Pain*, 10, 127-135.
- Mental Capacity Act. (2007), *Chapter 12*. Retrieved from [http://www.opsi.gov.uk/acts/acts2007/ukpga\\_20070012\\_en\\_1](http://www.opsi.gov.uk/acts/acts2007/ukpga_20070012_en_1)
- Merskey, H., & Bogduk, N. (1994). *Classification of Chronic Pain. Descriptions of Chronic Pain Syndromes and Definitions of Pain Terms*. (2<sup>nd</sup> ed.). Seattle: IASP.



- Miles, A., Curran, H. V., Pearce, S., & Allan, L. (2005). Managing constraints: The experience of people with chronic pain. *Social Science & Medicine*, 61(2), 431–441.
- Mills, J., Chapman, Y., Bonner, A., & Francis, K. (2007). Grounded theory: A methodological spiral from positivism to postmodernism. *Journal of Advanced Nursing*, 58(1), 72–79.
- Monhemius, R., & Simpson, B. A. (2003). Efficacy of spinal cord stimulation for neuropathic pain: Assessment by abstinence. *European Journal of Pain*, 7, 513-519.
- Morley, S. (2008). Psychology of pain. *British Journal of Anaesthesia*, 101(1), 25-31.
- Morken, I. M., Severinsson, E., & Karlsen, B. (2009). Reconstructing unpredictability: experiences of living with an implantable cardioverter defibrillator over time. *Journal of Clinical Nursing*, 19, 537-546.
- National Institute of Health and Clinical Excellence. (2008). *Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin*. Retrieved from <http://www.nice.org.uk/nicemedia/live/12082/42367/42367.pdf>
- Newton, B. J., Southall, J. L., Raphael, J. H., Ashford, R. L., & LeMarchand, K. (2010). A narrative review of the impact of disbelief in chronic pain, *Pain Management Nursing*, 1-11.
- Nicholson, B., & Verman, S. (2004). Comorbidities in chronic pain. *Pain medicine*, 5(S1), S9-S27.

- North, R. B., & Shipley, J. (2007). Practice parameters for the use of spinal cord stimulation in the treatment of chronic neuropathic pain. *Pain Medicine*, 8(S4), S200-S275.
- Oaklander, A. L. (1999). The pathology of shingles: Head and Campbell's 1900 monograph. *Archives of Neurology*, 56(10), 1292-1294.
- O'Connor, A. B. (2009). Neuropathic pain: Quality-of-life impact, costs and cost effectiveness of therapy, *Pharmacoeconomics*, 27(2), 95-112.
- Ohnmeiss, D. D., & Rashbaum, R. F. (2001). Patient satisfaction with spinal cord stimulation for predominant complaints of chronic, intractable low back pain. *The Spine Journal Official Journal of the North American Spine Society*, 1(5), 358–363.
- Olsen, W. K. (2004). Triangulation in social research: Qualitative and quantitative can really be mixed. In M. Holborn and M. Haralambos (Eds.), *Developments in Sociology: An annual review*. Ormskirk: Causeway Press.
- Opdenakker, R. (2007). Advantages and disadvantages of four interview techniques in qualitative research. *Forum: Qualitative social research*, 7(4). Retrieved from <http://nbn-resolving.de/urn:nbn:de:0114-fqs0604118>.
- Osborn, M. & Smith, J.A. (1998). The personal experience of chronic benign lower back pain. *British Journal of Health Psychology*, 3, 65–83.

- Osborn, M., & Smith, J. A. (2006). Living with a body separate from the self: The experience of the body in chronic benign low back pain: an interpretative phenomenological analysis. *Scandinavian Journal for Caring Sciences*, 20, 216-222.
- Ponterotto, J. G. (2005). Qualitative research in counseling psychology: A primer on research paradigms and philosophy of science. *Journal of Counseling Psychology*, 52(2), 126–136.
- Potter, J., & Wetherell, M. (1987). *Discourse and social psychology: Beyond attitudes and behaviour*. London: Sage.
- Price, D. D. (1999). *Psychological mechanisms of pain and analgesia*. Seattle, WA: IASP Press.
- Reid, K., Flowers, P., & Larkin, M. (2005). Exploring lived experience. *The Psychologist*, 18(1), 20-23.
- Richards, J., & Hubbert, A. O. (2007). Experiences of expert nursing in caring for patients with postoperative pain. *Pain Management Nursing*, 8(1), 17-24.
- Richardson, E. J., Ness, T. J., Doleys, D. M., Baños, J. H., Cianfrini, L., & Richards, J. S. (2009). Depressive symptoms and pain evaluations among persons with chronic pain: Catastrophizing, but not pain acceptance, shows significant effects. *Pain*, 147, 147–152.
- Schmitz, U., Saile, H., & Nilges, P. (1996). Coping with chronic pain: Flexible goal adjustment as an interactive buffer against pain-related distress. *Pain*, 67(1), 41-51.

- Shenton, A. K. (2004). Strategies for ensuring trustworthiness in qualitative research projects. *Education for Information*, 22(2), 63-75.
- Simpson, B. A. (1997). Spinal Cord Stimulation. *British Journal of Neurosurgery*, 11(1), 5-11.
- Simpson, E. L., Duenas, A., Holmes, M. W., Papaioannou, D., & Chilcott, J. (2009). Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: Systematic review and economic evaluation. *Health Technology Assessment*, 13(17), iii, ix-x, 1-157. doi: 10.3310/hta13170.
- Sindrup, S. H., & Jensen, T.S. (1999). Efficacy of pharmacological treatments of neuropathic pain: An update and effect related to mechanism of drug action. *Pain*, 83(3), 389-400.
- Smith, J. A. (1996). Beyond the divide between cognition and discourse: Using interpretative phenomenological analysis in health psychology. *Psychology Health*, 11(2), 261-271.
- Smith, J. A. (2004). Reflecting on the development of interpretative phenomenological analysis and its contribution to qualitative research in psychology. *Qualitative Research in Psychology*, 1(1), 39-54.
- Smith, J. A. (2011). Evaluating the contribution of interpretative phenomenological analysis, *Health Psychology Review*, 5(1), 9-27.
- Smith, J. A., Flowers, P., & Larkin, M. (2009). *Interpretative phenomenological analysis: Theory, method and research*. London: Sage.

- Smith, J. A., & Osborn, M. (2007). Pain as an assault on the self: An interpretative phenomenological analysis of the psychological impact of chronic benign low back pain. *Psychology and Health, 22*(5), 517-534.
- Smith, J. A. & Osborn, M. (2008). Interpretative Phenomenological Analysis. In J. Smith (Ed.), *Qualitative Psychology: A Practical Guide to Research Methods*. (2<sup>nd</sup> Ed., pp. 53-80). London: Sage.
- Smith, B. H., & Torrance, N. (2010). Neuropathic pain. In P.R. Croft, F. M. Blyth, & D. van der Windt (Eds.), *Chronic pain epidemiology: From aetiology to public health* (pp. 209-234). Oxford: Oxford University Press.
- Snelgrove, S., & Liossi, C. (2009). An interpretative phenomenological analysis of living with chronic low back pain. *British Journal of Health Psychology, 14*, 735-749.
- Snow-Tyrek, A., Norris, M. P., & Tan, G (1996). Active and passive coping strategies in chronic pain patients. *Pain, 64*(3), 455-462.
- Sofaer-Bennett, B., Walker, J., Moore, A. P., Lamberty, J., Thorp, T., & O' Dwyer, J. (2007). The social consequences for older people of neuropathic pain: A qualitative study. *Pain Medicine, 8*(3), 263-270.
- Sparkes, J. H., Raphael, J. H., Duarte, R. V., LeMarchand, K., Jackson, C., & Ashford, R. L. (2010). A systematic literature review of psychological characteristics as determinants of outcome for spinal cord stimulation therapy. *Pain 150*(2), 284-289.

- Sullivan, M. J., Lynch, M. E., & Clarke, A. J. (2005). Dimensions of catastrophic thinking associated with pain experience and disability in patients with neuropathic pain conditions. *Pain* 113, 310-315.
- Tagney, J., James, J. E., & Albarran, J. W. (2003). Exploring the patient's experiences of learning to live with an implantable cardioverter defibrillator (ICD) from one UK centre: A qualitative study. *European Journal of Cardiovascular Nursing*, 2(3), 195-203.
- Taylor, R. S. (2006). Epidemiology of refractory neuropathic pain. *Pain Practice*, 6(1), 22-26.
- Taylor, R. S., Van Buyten, J., & Buchser, E. (2006). Spinal cord stimulation for complex regional pain syndrome: A systematic review of the clinical and cost effectiveness literature and assessment of prognosis factors. *European Journal of Pain*, 10(2), 91-101.
- The British Pain Society. (2009). *Spinal cord stimulation for the management of pain: Recommendations for best clinical practice*. London: The British Pain Society. Retrieved from [http://www.britishpainsociety.org/book\\_scs\\_main.pdf](http://www.britishpainsociety.org/book_scs_main.pdf)
- Thorn, B. E., Boothby, J. E., & Sullivan, M. J. (2002). Targeted treatment of catastrophizing for the management of chronic pain. *Cognitive and Behavioural Practice*, 9(2), 127-138.
- Torrance, N., Smith, B. H., Bennett, M. I., & Lee, A. J. (2006). The epidemiology of chronic pain of predominantly neuropathic origin. Results from a general population survey. *Journal of Pain*, 7(4), 281-289.

- Turk, D. C., & Burwinkle, T. M. (2005). Clinical outcomes, cost-effectiveness, and the role of psychology in treatment for chronic pain sufferers. *Professional Psychology Research and Practice, 36*(6), 602-610.
- Turk, D. C., & Okifuji, A. (2002). Psychological factors in chronic pain: Evolution and revolution. *Journal of Consulting and Clinical Psychology, 70*(3), 678-690.
- Turner, J. A., Loeser, J. D., Deyo, R. A., & Sanders, S. B. (2004). Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications. *Pain, 108*, 137-147.
- Van Dorsten, B. (2006). Psychological considerations in preparing patients for implantation procedures. *Pain Medicine, 7*, S47-S57.
- Viane, I., Crombez, G., Ecclestone, C., Devulder, J., & De Corte, W. (2004). Acceptance of the unpleasant reality of chronic pain: Effects upon attention to pain and engagement with daily activities, *Pain, 112*(3), 282-288.
- Vowles, K. E., McCracken, L. M., & Eccleston, C. (2007). Processes of change in treatment for chronic pain: The contributions of pain, acceptance, and catastrophising. *European Journal of Pain, 11*(7), 779-787.
- Waddell, G., Newton, M., Henderson, I., Somerville, D., & Main, C. J. (1993). A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain, 52*(2), 157-168.

- Walker, J., Holloway, I., & Sofaer, B. (1999). In the system: The lived experience of chronic pain from the perspective s of those seeking help from pain clinics. *Pain*, 80(3), 621-628.
- Walker, J., Sofaer, B., & Holloway, I. (2006). The experience of chronic back pain: Accounts of loss in those seeking help from pain clinics. *European Journal of Pain*, 10(3), 199-207.
- Wertz, F. (2005). Phenomenological research methods for counseling psychology. *Journal of Counseling Psychology*, 52(2), 167-177.
- Willig, C. (2008a). *Introducing Qualitative Research in Psychology*. (2<sup>nd</sup> ed.). Maidenhead: Open University Press.
- Willig, C. (2008b). Discourse analysis. In J. A. Smith (Ed.), *Qualitative Psychology: A Practical Guide to Research Methods* (pp. 160-185). London: Sage Publications Ltd.
- Yardley, L. (2000). Dilemmas in qualitative health research. *Psychology & Health*, 15(2), 215-228.
- Yardley, L. (2008). Demonstrating validity in qualitative psychology. In J. A. Smith (Ed.), *Qualitative Psychology: A Practical Guide to Research Methods* (pp. 235-251). London: Sage Publications Ltd.



## **APPENDICES**

## Systematic Review

### Appendix A: Common neuropathic pain conditions

Neuropathic Pain Condition	Description
Failed Back Surgery Syndrome (FBSS)	FBSS describes patients experiencing persistent low back pain and leg pain as a result of unsuccessful back or spine surgery. Patients with greater leg pain as opposed to back pain are suggested to be suitable candidates for SCS. Many patients experience this type of pain following lumbar surgery (Medical Advisory Secretariat, 2005).
Complex Regional Pain Syndrome (CRPS) Type I (formally known as Reflex Sympathetic Dystrophy; RSD)	CRPS Type I is where symptoms (e.g. burning pain) develop in a limb, usually after an injury (e.g. a fracture) or immobilisation (e.g. stroke; Medical Advisory Secretariat, 2005), but are often disproportionate to the inciting event (Kemler et al., 2004). However, it can also start spontaneously with no precipitating injury. Patients experience allodynia which is a heightened sensitivity to touch and abnormal sweating.
Complex Regional Pain Syndrome (CRPS) Type II (formally known as causalgia – nerve injury)	Type II has a known nerve injury.
Postherpetic Neuralgia	This is a persistent pain, which occurs after having shingles. Some people experience sensory loss and allodynia in areas where they previously had shingles (Oaklander, 1999).
Diabetic Neuropathy	Symmetrical sensory loss and burning pain in the lower leg (Gillon, Watson, Cahill, & Moulin, 2006).
HIV-related Neuropathy	Painful paresthesia (abnormal sensations like numbness, itching or tingling) which is most pronounced in the toes and soles of the feet (Brew, 2003).

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**Full references are in the extended paper reference list**

## Appendix B: Systematic reviews of spinal cord stimulation surgery (NP and CP conditions including NP)

Author & Year	Title	Participants
Frey et al., 2009	Spinal Cord Stimulation for Patients with Failed Back Surgery Syndrome: A Systematic Review	Failed Back Surgery Syndrome (FBSS) patients
Simpson et al., 2009	Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation	Patients with FBSS, Complex Regional Pain Syndrome (CRPS), low back pain, Critical Limb Ischemia (CLI), and angina
Turner et al., 2004	Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications	FBSS, CRPS,
Celestin et al., 2009	Pretreatment Psychosocial Variables as Predictors of Outcomes Following Lumbar Surgery and Spinal Cord Stimulation: A Systematic Review and Literature Synthesis	Chronic back pain
Mailis-Gagnon et al., 2009	Spinal cord stimulation for chronic pain (Cochrane Review)	Chronic pain
Taylor et al., 2006	Spinal Cord Stimulation in Complex Regional Pain Syndrome and Refractory Neuropathic Back and Leg Pain/Failed Back Surgery Syndrome: Results of a Systematic Review and Meta-Analysis	CRPS and FBSS
Taylor et al., 2005	Spinal cord stimulation for chronic back and leg pain and failed back surgery syndrome: a systematic review and analysis of prognostic factors	FBSS and chronic back and leg pain
Grabow et al., 2004	Spinal Cord Stimulation for Complex Regional Pain Syndrome: An evidence Based Medicine Review of the Literature	CRPS
Mailis-Gagnon et al., 2004	Spinal Cord Stimulation	Chronic pain

### **Appendix C: Search strategy** (example medline search strategy)

1. (spinal-cord stimulat\* or spinal cord stimulat\*).mp
2. exp Electric Stimulation Therapy/
3. exp Electric Stimulation/
4. neurostimulat\*.mp.
5. 1 or 2 or 3 or 4
6. "quality of life".mp.
7. (euroqol or euro qol or eq5d or eq 5d).mp.
8. (hql or hqol or h qol or hrqol or hr qol).mp.
9. ("nottingham health profile" or NHP).mp.
10. (sf36 or sf 36 or short form 36 or shortform thirty six or short form thirty six).mp.
11. anxi\*.mp.
12. depress\*.mp.
13. mood.mp.
14. psych\*.mp.
15. (physical activit\* or social activit\*).mp.
16. "activities of daily living".mp.
17. mobility.mp.
18. (work or employ\*).mp.
19. (pain or discomfort).mp.
20. "self care".mp.
21. 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20
22. 5 and 21
23. outcome\*.mp.
24. exp "Outcome and Process Assessment (Health Care)"/
25. exp "Outcome Assessment (Health Care)"/
26. exp Treatment Outcome/
27. 23 or 24 or 25 or 26
28. 22 and 27
29. neuropathic pain.mp.
30. 28 and 29
31. limit 30 to humans

**Appendix D: Data extraction pro-forma**  
(adapted from Torgerson, 2003)

**Trial & Study:**

**Author & Year:**

**Objectives:** *(Are the aims clearly stated?)*

**Study Design:** *(What is the study design?)*

**Setting & Country:** *(Was it a single or multicentre site? Which country/countries were the sites based in?)*

**Treatment Period:** *(Was the period of time participants received treatment stated? What was this time period?)*

**Participants:** *(What was the total number of participants? How many participants were in each group? What was the mean age of participants in each group? What was the age range? What is the neuropathic pain condition?)*

**Pre-screening/Trial stimulation:** *(Was pre-screening for psychological factors conducted? Did patients have trial stimulation prior to implantation of the SCS?)*

**Intervention and Comparator:** *(What was the intervention group? What was the comparator?)*

**Outcomes Measures:** *(What outcome measures were used?)*

**Follow up:** *(What was the follow up time period?)*

**Key findings:** *(What were the key findings related to Quality of Life as evaluated using generic measures? Were there any changes in pain intensity?)*

## Appendix E: A: Table to show study characteristic for Prospective Randomised Controlled Trial of Effectiveness of SCS (PROCESS) trial

Trial & Study	Author & Date	Objectives	Study Design	Setting & Country	Treatment Period	Participants	Pre-screening/ Trial	Intervention & comparator	Outcome Measures	Follow up
A1	Kumar et al (2007)	To assess the effectiveness of SCS+ CMM compared with CMM alone.	PROCESS	Multisite  12 sites (Europe, Canada, Australia & Israel)	April 2003-2005	100 <b>Baseline:</b> SCS+CMM = 52, M = 30, F =22, Mean Age = 48.9 years; CMM = 48, M =21, F = 27, Mean Age = 52.0 year NP = Radicular origin predominantly in legs	Trial stimulation undertaken	SCS+CMM  Vs  CMM	-VAS = At least 50% pain relief -SF36 -ODI -Patient satisfaction -Changes in pain medication and non drug therapies -Employment Status -Complications were listed	Reported on 6 & 12 Months.   Could request crossover at 6months.
A2	Kumar et al (2008)	To assess the effectiveness of SCS+CMM, compared with CMM alone at 24 month follow up	PROCESS	Multisite  12 sites (Europe, Canada, Australia & Israel)	April 2003-2005	42 <sup>8</sup> <b>24 months:</b> SCS+CMM: M=25, F=17, Mean Age = 48.8 years; CMM (n=10): M=5, F=5, Mean Ages = 49.2 years NP same as A1.	Trial stimulation undertaken	SCS+CMM  &  CMM <sup>9</sup>	-VAS = At least 50% pain relief -SF36 & EQ-5D -ODI -Patient satisfaction -Changes in pain medication and non drug therapies -Employment Status -Complications listed	Reported on 24 months

<sup>8</sup> = Study based on patients in A1; however only those randomly assigned to SCS+CMM were included in A2, not patients who crossed over at 6 months

<sup>9</sup> = No. of patients randomised to and remaining in the CMM group were too small to use as comparison analysis (n=11); analysis performed for illustrative purposes only.

A3	Manca et al. (2010)	To quantify the extent to which reduction in leg & back pain & disability over time translate to improvement in HRQoL	PROCESS	Multisite  12 sites (Europe, Canada, Australia & Israel)	April 2003-2005	<b>100</b> <b>Baseline:</b> SCS+CMM = 52, M = 30, F =22, Mean Age = 48.9 years; CMM = 48, M =21, F = 27, Mean Age = 52.0 years. <b>-6 months N/S.</b> -NP same as A1.	Trial stimulation undertaken	SCS+CMM  &  CMM	-VAS = At least 50% pain relief -SF36 & EQ-5D -ODI -Patient satisfaction -Changes in pain medication and non drug therapies -Employment Status -Complications were listed	Reported on Baseline & 6 months
A4	Eldabe et al (2010)	To analyse the sub-dimensions of Health outcomes related to pain, functions and HRQoL	PROCESS	Multisite  12 sites (Europe, Canada, Australia & Israel)	April 2003-2005	100 <b>Baseline:</b> SCS+CMM = 52, M = 30, F =22, Mean Age = 48.9 years; CMM = 48, M =21, F = 27, Mean Age = 52.0 years. <b>- 6 months N/S.</b> NP as A1.	Trial stimulation undertaken	SCS+CMM  &  CMM	-VAS = At least 50% pain relief -SF36 & EQ-5D -ODI -Patient satisfaction -Changes in pain medication and non drug therapies -Employment Status -Complications were listed	Reported on Baseline, 6 months & 24 months

KEY: CMM = Conventional Medical Management (e.g. oral medication, nerve blocks, psychological rehabilitation); EQ-5D = European Quality of Life measure; HRQoL = Health Related Quality of Life; NP = Neuropathic Pain; ODI = Oswestry Disability Inventory; SCS = Spinal Cord Stimulation; SF-36 = Short Form-36 (HRQoL measure); VAS = Visual Analogue Scale

## Appendix E: B: Table to show study characteristic for Kemler prospective randomised controlled trials

Trial & Study	Author & Date	Objectives	Study Design	Setting & Country	Treatment Period	Participants	Pre-screening/ Trial	Intervention & comparator	Outcome Measures	Follow up
B5	Kemler et al. (2000)	To assess the effectiveness of SCS+PT compared with PT alone for chronic reflex sympathetic dystrophy (RSD).	Prospective RCT	Single site Netherlands	March 1997- July 1998	54 <b>Baseline:</b> SCS+PT = 36, M = 14, F =22, Mean Age = 40.0 years PT = 18, M =3, F = 15, Mean Age = 35.0 years  Met Criteria CRPS (formally known as RSD). Disease restricted to one extremity, however affected whole hand or foot	Pre-Screening For Psychological distress  &  Trial stimulation undertaken	SCS+PT <sup>10</sup>  Vs  PT	-VAS & MPQ -GPE scale -Functional Status: Functional test of hand & functional test of the foot. -A Jamar dynamometer was used to measure grip strength -A hand held myometer was used to measure strength of foot dorsiflexion and plantar -NHP & EQ-5D -SIP -SRDS <sup>11</sup> -Adverse events listed	Reported 6 months

<sup>10</sup> = Physical Therapy (PT) was a standardised program of graded exercises to improve strength, mobility, and function of the affected hand or foot. Administered for 30 minutes twice a week, with a minimum of 2 days between sessions, total duration = 6 months. Selected physical therapists were trained to do the program to ensure standardisation.

<sup>11</sup> = All questionnaires had been previously validated then translated to Dutch.



B6	Kemler et al. (2004)	To assess the effectiveness of SCS+PT compared with PT alone for chronic RSD at 2 years.	Prospective RCT	Single site Netherlands	March 1997- July 1998	21 2 years: SCS+PT = 35 & PT = 16. No further demographics provided  As B5 met criteria CRPS.	As in B5	SCS+PT  &  PT	As in B5	Reported difference between baseline & 24 months
B7	Kemler et al. (2008)	To assess the effectiveness of SCS+PT compared with PT alone for chronic RSD at 5 years.	Prospective RCT	Single site Netherlands	March 1997- July 1998	36 5 years: SCS+PT = 31 & PT = 13. No further demographic provided  As B5 met criteria CRPS.	As in B5	SCS+PT  &  PT	As in B5	Reported difference between baseline and 60 months

KEY: CRPS = Complex Regional Pain Syndrome; GPE = Global Perceived Effect Scale; MPQ = McGill Pain Questionnaire; NHP = Nottingham Health Profile; SRDS = Self Rating Depression Scale; SIP = Sickness Impact Profile.

## Appendix E: C: Table to show study characteristic of included case series

Trial & Study	Author & Date	Objectives	Study Design	Setting & Country	Treatment Period	Participants	Pre-screening/ Trial	Intervention & comparator	Outcome Measures	Follow up
8	Van Buyten et al. (2008)	To assess patients ability to recharge the neurostimulator and clinical effectiveness of SCS.	Case Series  - pre & post treatment comparison	Multisite  12 sites  European Centres  Specific countries N/S	October 2004- March 2005	45 M = 15 F =30  Mean Age = 51.3 years (ranging 31.1 to 69.4)  Chronic NP patients: 55% FBSS: post-operative back or leg pain, 27% radicular pain, 7% CRPS I, 7% CRPS II & 4% other	Trial stimulation undertaken	SCS  No comparator	-VAS -EQ-5D -ODI -1-5 rating scale of patient and physician satisfaction with neurostimulator -Complications listed	Reported difference between baseline & 12 months  Last 12 month follow up April 2006

9	Spince maile et al. (2004)	To build a quality system for neuromodul ation	Case Series  - pre & post treatment comparison	Single site  Netherlands	April 1999- December 2001	105 M = 43% F = 57%  Mean Age = 52.5 years  FBSS: Neuropathic Limb Pain 12.4 % = only leg pain (type II) 87.6% = Pain in one leg and some back pain (type III)	Pre-screening: SCL-90  Trial stimulation undertaken	SCS and regular treatment (including physiotherapy, TENS, oral medication such as anti- depressants, NSAIDs and analgesics)  No comparator	-VAS -MPQ -MQS -EQ-5D -SIP -RD No complication reported	Reported difference between baseline & 12 months  96 participants left @ 12 months
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KEY: MQS = Medication Quantification Scale; NSAID = Non-steroidal anti-inflammatory drugs; RD= Roland Disability Scale; TENS = Transcutaneous electrical nerve stimulation

## Appendix F: Key findings of pain intensity and health related quality of life

Study	Follow Up	Key Findings
A1	6 month	<ul style="list-style-type: none"> <li>• More SCS patients achieved the primary outcome of 50% pain relief (48% of SCS group vs 9% of CMM group).</li> <li>• Compared to the CMM group, the SCS group achieved lower levels of leg pain (<math>p &lt; 0.0001</math>) and lower levels of back pain (<math>p = 0.008</math>).</li> <li>• The SCS group exhibited enhanced HRQoL on seven of the eight domains on the SF-36 (<math>p \leq 0.02</math>) except on role-emotional. CMM only improved significantly in one out of the eight domains compared with baseline which was 'general health' (<math>p &lt; 0.007</math>).</li> </ul>
	12 month	<ul style="list-style-type: none"> <li>• More SCS patients achieved over 50% pain relief than the CMM alone group on both an as per treatment analysis (48% of SCS group vs 18% CMM group, <math>p = 0.03</math>).</li> <li>• An intention to treat analysis was completed categorising patients who crossed over at 6 months as not meeting the primary outcome. Difference between groups achieving the primary outcome remained similar (34% of SCS group vs 7% of CMM, <math>p = 0.005</math>).</li> <li>• HRQoL results were not reported at 12 months.</li> </ul>
A2	24 months	<ul style="list-style-type: none"> <li>• Compared with baseline, SCS patients experienced lower levels of leg pain (<math>p &lt; 0.0001</math>) but there was no significant difference in back pain (<math>p = 0.21</math>).</li> <li>• Compared with baseline, SCS patients experienced enhanced HRQoL on the EQ-5D (<math>p &lt; 0.0001</math>) and on 7 of 8 domains of the SF36 (<math>p \leq 0.01</math>) except for role-emotional (<math>p = 0.11</math>). EQ-5D sub-dimensions were not reported.</li> <li>• Illustrative analysis was completed (due to low numbers in CMM group, <math>n=11</math>), showed over 37% patients in SCS group and 2% in the CMM alone group achieved the primary outcome of 50% leg pain relief (<math>p &lt; 0.0003</math>).</li> <li>• No HRQoL comparisons were completed.</li> </ul>

A3 <sup>12</sup>	6 months	<ul style="list-style-type: none"> <li>• The degree of association between patient's pain levels, disability and generic HRQoL depended on the HRQoL measure and the dimensions of the HRQoL being investigated.</li> <li>• Pair wise correlation co-efficients revealed, at baseline, significantly greater levels of leg pain on the disease-specific measure were associated with lower levels of generic HRQoL, as measured by the EQ-5D (EQ-5D vs leg pain: <math>r=-0.436</math>, <math>p&lt;0.05</math>).</li> <li>• The functional ability (ODI) showed a statistically significant negative correlation with all generic HRQoL measures (EQ-5D: <math>r=-0.638</math>, <math>p&lt;0.05</math>, MCS: <math>r=-0.301</math>, <math>p&lt;0.05</math>, PCS: <math>r=-0.462</math>, <math>p&lt;0.05</math>) indicating lower functional disability is associated with higher generic HRQoL regardless of the generic HRQoL measure employed.</li> <li>• Multilevel regression analyses revealed a number of baseline characteristics such as age, genders, and location of pain, were not statistically significant predictors of generic HRQoL in the first 6 months of the study.</li> <li>• The EQ-5D regression model indicated higher leg pain and functional disability are significantly associated with lower EQ-5D (leg pain: <math>r=-0.039</math>; coefficient for ODI: <math>r=-0.069</math>, all <math>p&lt;0.001</math>).</li> </ul>
A4	Baseline, 6 & 24 months	<ul style="list-style-type: none"> <li>• More SCS patients (68%) experienced at least 30% leg pain relief in comparison to CMM alone (18%).</li> <li>• The SCS group got significantly greater scores on the PCS &amp; MCS components of the SF-36 and there was a significant improvement from baseline which was sustained at 24 months.</li> <li>• The SCS group reported greater improvements when compared with CMM and baseline in 4 out of 5 dimensions: anxiety/depression, pain/discomfort, self care, and usual activities (all <math>p\leq0.05</math>), which were sustained at 24 months.</li> <li>• SCS provided pain relief, improvement in most sub-dimensions of HRQoL and functional capacity, where as CMM alone provided little or no pain relief or other improvements.</li> <li>• Most improvement with SCS were sustained at 24 months, however 36% still reported HRQoL problems, related to pain and discomfort being an extreme problem.</li> </ul>

<sup>12</sup> = Key finding of Study A3 will report results of both generic and specific measures to fulfil the review objective as the purpose of this article was to explore the associations between these measures.

B5	6 months	<ul style="list-style-type: none"> <li>ITT analysis revealed SCS patients reported a reduction in pain of 50% or more. No figure was provided for the PT group. VAS scores suggest SCS patients had a larger pain reduction (mean = -2.4cm) in comparison to PT alone where there was an increase in scores (mean = 0.2cm, <math>p &lt; 0.001</math>).</li> <li>The ITT analysis revealed no significant differences in HRQoL between groups.</li> <li>A multivariate regression showed that no baseline factor other than treatment allocation influenced the size of the effect.</li> <li>Per treatment analysis suggested SCS patients (n=24) experienced a larger pain reduction on VAS scores (mean = 3.6cm) in comparison to PT alone (mean increase = 0.2cm). HRQoL significantly improved for those affected in the hand (<math>p = 0.02</math>) and those affected in the foot (<math>p = 0.08</math>). This effect was chiefly derived from the pain component of the Nottingham Health Profile which is the primary source of distress of this patient population.</li> <li>Other generic measures of HRQoL (i.e. EQ-5D) and more specific HRQoL measures (e.g. SIP) or the Self Rating Depression Scale (SRDS) were not reported.</li> </ul>
B6	2 years	<ul style="list-style-type: none"> <li>ITT analysis revealed SCS groups showed a reduction in pain (mean VAS = 2.1cm) whereas the PT showed no reduction (Mean 0cm, <math>p &lt; 0.001</math>).</li> <li>A multivariate regression showed that no baseline factor other than treatment allocation influenced the size of the effect.</li> <li>No statistically significant changes were observed in HRQoL.</li> <li>Per treatment analysis revealed improvements in pain relief only in the 24 SCS patients (mean pain relief = 3.0cm) and improvements in HRQoL on the pain component of the NHP for upper (<math>p = 0.02</math>) and lower (<math>p = 0.008</math>) extremities.</li> <li>The EQ-5D results were not reported.</li> </ul>
B7	5 Years	<ul style="list-style-type: none"> <li>Results indicated that the pain alleviating effect of SCS in patients with chronic CRPS-I diminished over time, which were no longer significant at 3 year follow up.</li> <li>Of the 31 patients remaining in the SCS group at 5 years, there was a reduction of pain intensity (mean -1.7cm), which was more than the 13 patients in the PT alone group (-1.0cm; <math>p = 0.25</math>). However, it was not statistically significant.</li> <li>A multivariate regression showed that no baseline factor other than treatment allocation influenced the magnitude of effects.</li> <li>HrQoL measures for the EQ-5D and NHP indicated no significant changes between groups.</li> <li>Per treatment analysis of patients implanted with a SCS (n=20) revealed reduction in pain (mean VAS = 2.5cm) in comparison to PT alone (mean VAS = 1.0cm, <math>p = 0.06</math>). SCS did not influence HRQoL scores.</li> <li>Despite the above, 18 of the 20 patients with an implant (90%) indicated they had positively responded to treatment and 19 (95%) reported they would undergo the treatment again for the same outcomes.</li> </ul>

8	12 months	<ul style="list-style-type: none"> <li>• The rechargeable neurostimulator was successfully recharged by all patients meeting the primary objective to achieve between 75-95% success rates.</li> <li>• Favourable satisfaction ratings were observed for the neurostimulation system from both patients (97.6%) and physicians (92.7%).</li> <li>• Pain improved over the 12 month period with mean VAS scores reducing significantly (baseline = 7.2 to 12 months = 4.4, <math>p&lt;0.001</math>) and 80.5% of patients reported at least 50% pain relief in the primary area of pain.</li> <li>• SCS resulted in improvements in HRQoL as measured by the EQ-5D with the mean scored doubling (baseline = 0.21 to 12 months = 0.46, <math>p&lt;0.001</math>). Subscales were not reported.</li> <li>• 93% reported they would undergo the same procedure to get the same results.</li> </ul>
9	12 months	<ul style="list-style-type: none"> <li>• Authors did not discuss the results of their statistical analyses; they presented mean scores for each outcome in a table showing baseline and 12 months results.</li> <li>• Mean VAS scores suggested significant reductions in pain (baseline 7.3 to 12 months = 3.0, <math>p&lt;0.05</math>) and the EQ-5D suggested significant improvements in HRQoL (baseline = 55.2 to 12 months = 12.4, <math>p&lt;0.05</math>). Subscales of EQ-5D measures were not reported but SIP subscales were reported.</li> </ul>

## Appendix G: Outcome measures in reviewed studies

Outcome measure	Measure description
Visual Analogue Scale (VAS)	The VAS measures pain intensity. It is often a straight horizontal line 100 mm long with 'no pain' on the left hand side and 'worst pain imaginable' on the right hand side. The patient marks their pain magnitude on the scale and the physician measures the distance in mm from the left hand side to ascertain a number (e.g. patient mark 70mm along, so the VAS score is 70). It is noted to be used across cultures and relatively sensitive, with it being commonly used in research <sup>9</sup> . However, there are many variations of its use.
McGill Pain Questionnaire (MPQ) <sup>7</sup>	MPQ measures pain part one, consists of 3 major classes of word descriptors of pain: sensory, affective and evaluative. Part two has a scale to measure pain intensity. Part one ranged from 0-20, higher scores indicate more pain and part two contained scores ranging from 0-63. Higher scores indicate more pain.
Jebsen Functional test for the hand	To measure hand function by timing the patient doing a range of tasks.
Kemler functional test for the foot <sup>5</sup>	To measure foot function by timing the patient doing a range of tasks.
Global Perceived Effect	Perception of effect is rated on a seven point scale (1, worst ever; 2 much worse; 3 worse; 4 not improved and not worse; 5 improved; 6 much improved and 7 best ever) <sup>4</sup> .



Oswestry Disability Index (ODI) <sup>2</sup>	The ODI is a measure of disability which consists of 7 categories: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life (if applicable) and social life. They all contain 6 statements (for example on the pain intensity scale the first statement 'I have no pain at the moment' and the last statement is 'the pain is the worse imaginable at the moment'. First statement score 0, the last statement score 5. Scores are obtained by dividing the total score by the total possible score and multiplying it by 100 to obtain a percentage. If the percentage of change is 10% or less it is attributed to error.
Nottingham Health Profile (NHP) <sup>3</sup>	This HRQoL measure is divided into two parts. Part One consists of 6 components: sleep, physical activities, energy, pain, emotional reactions and social isolation where respondents' rate simple statements. Each dimension has a range between 0-100. The second part consists of 7 statements related to areas of life that may be affected by health problems: employment, housework, social life, sex life, personal relationship, hobbies and interests and holidays. Scored 1 = yes and 0 = no. For some groups several items do not apply, for example the elderly, unemployed or disabled <sup>1</sup>
EuroQoL 5D (EQ-5D) <sup>6</sup>	This measures HRQoL through 5 domains: Mobility, activities, anxiety/depression, pain/discomfort and self care. The measure has two parts: Part One asks the respondent to rate their health state on the five domains described above, it provide three statements to choose from. For example, the mobility domain has these three statements; I have no problems walking around, I have some problems walking around, I am confined to bed. Part Two is a vertical scale from 0 – 100, 0 = worst imaginable health state and 100 = best imaginable health state. There are a number of ways to score the measure depending on the purpose (see <sup>6</sup> ).

Generic Short Form 36 (SF36) <sup>11</sup>	This measures HRQoL through two main scales, the physical component scale (PCS) and the mental component scale (MCS). It consists of eight domains: Physical functioning, Role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health <sup>11</sup> .
Short generic version Sickness Impact Profile (SIP)	68 item measures of HRQoL consisting of 6 subscales measuring activities of daily life, mobility and complex physical activities. There are scores for different diseases with minor diseases averaging between 10-15 and major diseases such as stroke and spinal cord lesions between 15-25.
Self Rating Depression Scale (SRDS) <sup>12</sup>	A measure of depression containing 20 items relating to depression where respondents have to rate how they have felt in the last week.
Medication Quantification Scale (MQS)	This consists of two components to evaluate the use of analgesics. The first part produces a detrimental weight to weigh up the harm caused by long term use. The second part is related to the dose recommended by manufacturers which ranges from 0 (<1 dose per week) to 4 (super-therapeutic dose). MQS scores are obtained for each medication by multiplying the detriment weight score by the dose level <sup>10</sup> .
Roland Disability (RD) <sup>8</sup>	It is measure which asks 24 questions focusing on lower back problems. A score is calculated by getting the sum of the positive answers.

## Appendix H: Quality assessment criteria (based on NHS CRD Report No.4)

### 1) Quality assessment of Randomised Controlled Trials

Quality Question	Trial: PROCESS	Kemler Trials
Was the method used to assign participants to the treatment groups really random?	Yes	Yes
What method of assignment was used?	1:1 randomisation. Biostatistician prepared random computer generated blocks (of two to four patients) on a per site basis.	After baseline assessment, 2:1 randomisation to receive SCS+PT or PT alone. Computer generated table of random numbers was used. Stratified according to the location of the RSD (hand or foot).
Was the allocation of treatment concealed?	Yes	Yes
What method was used to conceal the treatment allocation?	Randomisation was electronically locked and only accessed after a patient entered the trial	Allocation made by research assistant, by telephone, concealed from study investigators.
Was the number of participants who were randomised stated?	Yes	Yes
Were the group similar at baseline in terms of prognostic factors?	Yes	Yes
Were the eligibility criteria for the study entry specified?	Yes.	Yes
Were details of baseline comparability presented?	Majority excluding back pain.	Yes
Was an intention-to-treat analysis included?	Yes	Yes
Were at least 80% of the participants originally included in the randomised process followed up in the final analysis?	Yes	Yes

## 2) Quality assessment of case series:

Quality Questions	Study 8	Study 9
<b>Is the study based on a representative sample selected from a relevant population?</b>	Yes (3 different neuropathic pain conditions: CBLP, CRPS, FBSS)	Yes
<b>Are the criteria for inclusion and exclusion explicit?</b>	Yes (but minimal = age, indication, medical history)	Yes
<b>Did all individuals enter the study at similar points in their condition progression?</b>	Various diagnoses	N/S but probably not
<b>Was follow-up long enough for important events to occur?</b>	Yes 12 months	Yes 12 months
<b>Were outcomes assessed using objective criteria or was blinding used?</b>	No. Outcome evaluator N/S.	No, third party outcome evaluator
<b>If comparison of sub-series are being made, sufficient description of the series and the distribution of the series and the distribution of prognostic factors?</b>	No subseries	No subseries

Key: Chronic Back and Leg Pain (CLBP); Complex Regional Pain Syndrome (CRPS); Failed Back Surgery Syndrome (FBSS); N/S = Not stated.

**Research Project**  
**Appendix I: Ethical approval letter**



**National Research Ethics Service**

Leicestershire, Northamptonshire & Rutland Research Ethics Committee 1



13 September 2010

Miss Anna Turner  
University of Nottingham  
International House  
I-WHO, Jubilee Campus  
Nottingham  
NG8 1BB

Dear Miss Turner,

<b>Study Title:</b>	<b>Spinal Cord Stimulation Surgery for Chronic Neuropathic Pain: The Psychological Experience of the Treatment Journey</b>
<b>REC reference number:</b>	<b>10/H0406/66</b>
<b>Protocol number:</b>	<b>10063</b>

The Research Ethics Committee reviewed the above application at the meeting held on 03 September 2010. Thank you for attending to discuss the study.

**Ethical opinion**

- You confirmed that participants do not normally lose the capacity to consent but can become very depressed and anxious due to their pain which could put their capacity into question. You acknowledged that this would be an extreme case and would not be highly likely.
- You clarified that the mention of contacting the participant's GP in the Participant Information Sheet was an error as the University of Nottingham informed you that there was no need to. The Committee stated that this information should be removed.
- The Committee asked who would make the assessment of the safety of the visit location. You stated that there was no mechanism to do this however you would make the necessary checks at the beginning and end of the visit. You mentioned that it would be possible to include this if the Committee deemed it necessary. The Committee suggested that you seek clarification regarding who should perform this and how; they informed you that this information should be included in the lone worker policy.
- The Committee informed you that the date of birth should be removed from the Demographic data sheet and you agreed to do this.
- The Committee stated that the Samaritans contact details should be removed from the Participant Information Sheet and you agreed to do so.
- The Committee informed you that clarification will be sought from the University of

This Research Ethics Committee is an advisory committee to East Midlands Strategic Health Authority  
*The National Research Ethics Service (NRES) represents the NRES Directorate within the  
National Patient Safety Agency and Research Ethics Committees in England*

WPH 1370

Nottingham as to whether the certificate of insurance that has been submitted is the correct one and you will be notified.

- You confirmed that you will be the principal investigator for the study and the Committee informed you that it was not a major issue that the term was not consistent throughout the IRAS form.

***The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.***

#### **Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

#### **Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study:

1. Clarification is required as to who will perform a safety assessment of the visit location and how this will be done. This information should be found in the lone worker policy so the Committee should just be notified for information only.
2. The reference to the participant's date of birth should be removed from the Demographic data sheet.
3. The contact details for the Samaritans group should be removed from page four of the Participant Information Sheet.
4. Point one of the Consent Form should be updated to refer to the new version number and date of the Participant Information Sheet.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.*

*Sponsors are not required to notify the Committee of approvals from host organisations.*

**It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

**You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers.**

### Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Investigator CV		09 August 2010
Protocol	1.0	29 July 2010
CV - Anna Turner		06 August 2010
Demographic Information	1.0	27 July 2010
REC application	52521/141158/1/8	09 August 2010
Covering Letter	1.0	27 July 2010
Letter from Sponsor		06 August 2010
Interview Schedules/Topic Guides	1.0	29 July 2010
Participant Information Sheet	1.0	29 July 2010
Participant Consent Form	1.0	29 July 2010
CV - Roshan das Nair		06 August 2010
Study Summary Request	1.0	27 July 2010
Evidence of insurance or indemnity		22 July 2010

### Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The investigator is a member of the school where Steve Barrett works however he has had no involvement in the development of the study.

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

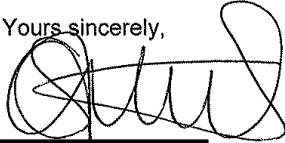
We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email [referencegroup@nres.npsa.nhs.uk](mailto:referencegroup@nres.npsa.nhs.uk).

10/H0406/66

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely,



Chair

Email: [redacted]

Enclosures:

*List of names and professions of members who were present at the meeting and those who submitted written comments  
"After ethical review – guidance for researchers"*


Copy to:

[redacted]  
R&D office for NHS care organisation at lead site – [redacted]

Professor N Lincoln – Chief Investigator



## Appendix J: R&D approval letter

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Please reply to:		
		Research and Development
		<div style="border: 1px solid black; height: 80px; width: 180px;"></div>
Telephone:		
Fax:		
E-mail:		

Miss Anna Turner  
I-WHO University of Nottingham  
International House  
B Floor, Jubilee Campus  
Wollaton Road  
NG8 1BB

04 October 2010

Dear Miss Turner

**ID: 10PT004      Spinal Cord Stimulation Surgery for chronic Neuropathic Pain: The Psychological Experience of the Treatment Journey**

The R&D Department has considered the following documents:

- . IRAS Application form, version 3.0
- . Protocol, version 2.0 dated 17/09/10
- . Demographic Information version 2.0 dated 17/09/10
- . Cover letter version 1.0 dated 27/07/10
- . Interview Schedules/Topic Guides version 1.0 dated 29/07/10
- . Information Sheet, version 2.0 dated 17/09/10
- . Participant consent form, version 2.0 dated 17/09/10
- . Study Summary Request version 1.0 dated 27/07/10

Your study now has R&D approval, on the understanding and provision that you will follow the conditions set out below.

### Conditions of Approval

That you:

1. Comply with all relevant laws, regulations and codes of practice applicable to the trial including but not limited to, the UK Clinical Trials Regulations, Medicines for Human Use (Clinical Trial) Regulations 2004, principles of Good Clinical Practice, the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects' (1996 version), the Human Rights Act 1998, the Data Protection Act 1998 the Medicines Act 1968, the NHS Research Governance Framework for Health and Social Care (version 2 April 2005). Should any of these be revised and reissued the latest version of the relevant laws and regulations will apply. Copies of the regulations are available from the R&D Office or via the R&D website <http://nuhrise.org>
2. For NUH sponsored studies accept the responsibilities as outlined in the "Clinical Trial Delegation of Sponsorship responsibilities to Chief Investigator" agreement.
3. Request written approval from the R&D department, Ethics Committee and MHRA (as appropriate) for any Protocol Amendments, changes to study documentation or changes to study team.
4. Ensure all study personnel, not employed by the  hold either honorary contracts/letters of access with this Trust, before they have access to any patients or staff, their data, tissue or organs or any NUH facilities.
5. According to R&D SOP 11 - "Adverse Event Monitoring, Recording and Reporting for investigators"

report any Serious Adverse Events to the R&D department.

6. According to R&D SOP 12 - "Protocol Violations and Serious Breach Reporting" report any Serious Breach of the UK Clinical Trial regulations in connection with the trial or Serious Breach of the protocol, immediately after becoming aware of the breach to R&D.

7. complete Annual Safety, Progress reports and End of Study reports as required by R&D, Ethics Committee and the MHRA.

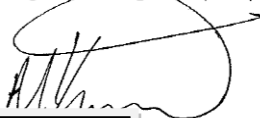
8. Notify R&D within 7 calendar days of the first patient or healthy volunteer recruited onto the study, as well as the detail of the specific recruitment date. Please email the recruitment notification to [rdmon@nuh.nhs.uk](mailto:rdmon@nuh.nhs.uk).

9. For GTAC-approved studies, the R&D approval letter should be forwarded to GTAC via the sponsor. GTAC should then issue a site authorisation letter which must be received by each site prior to recruitment commencing. A copy of the letter must be forwarded to R&D.

This approval letter constitutes a favourable Site Specific Assessment (SSA) for this site.

Please note that the R&D department has a database containing study related information, and personal information about individual investigators e.g. name, address, contact details etc. This information will be managed according to the principles established in the Data Protection Act.

Yours sincerely



[Redacted signature box]

**Director of R&D / Assistant Director Research and Innovation**

cc [Redacted email address]

[Redacted email address]

## **Appendix K: Covering letter sent out to participants**

### **Spinal Cord Stimulation Surgery for Chronic Neuropathic Pain: The Psychological Experience of the Treatment Journey**

Dear

The Department of Neurosurgery at the [REDACTED]  
[REDACTED] has sent you this information pack on behalf Anna Turner. She is currently training to be a Clinical Psychologist for the NHS with the University of Nottingham. She wanted me to contact you because you have recently undergone spinal cord stimulation surgery and she would like to invite you to take part in her research study.

The purpose of the research is to explore your experience of spinal cord stimulation surgery, specifically by discussing your experience of life before and after the surgery. The research intends to give you the opportunity to voice these experiences, with the aim of enhancing the understanding of the treatment experience for future patients, families, healthcare professionals, surgeons and the wider NHS. The research will be part of her Doctoral Thesis; therefore will count towards her qualification as a Clinical Psychologist.

Please take your time to read the information sheet enclosed. This provides details about the research. If you would like to take part in the research or would like to contact Anna for more information before deciding, please call her on her research study mobile on 07583419942 or alternatively email her [lwaxamt1@nottingham.ac.uk](mailto:lwaxamt1@nottingham.ac.uk) and she will get back to you as soon as possible. Thank you for your time.

Kind Regards,

[REDACTED] Consultant Neurosurgeon

Secretary [REDACTED]

## **Appendix L: Participant information sheet**

### **Spinal Cord Stimulation Surgery for Chronic Neuropathic Pain: The Psychological Experience of the Treatment Journey**

Researchers: Anna Turner (Principal Investigator), Prof. Nadina Lincoln (Chief Investigator), Dr. Roshan das Nair (Academic Supervisor) and Dr. Jamie Macniven (Clinical Supervisor).

I would like to invite you to take part in a research study. Before you decide I will explain why the research is being done and what your role would be. Please take your time to read the following information carefully. Please feel free to talk to others about the research if you wish. Also, you're welcome to contact me if you would like to ask me any questions if anything is unclear or if you would like more information. Take your time to decide whether or not you would like to take part in the research.

#### ***What is the purpose of the research?***

The purpose of the research is to explore the experience of patients who have undergone spinal cord stimulation surgery for chronic neuropathic pain. The aim is to gain an understanding of life both before and after the surgery. The research hopes to give patients an opportunity to discuss their experience, with the goal of promoting an understanding for other patients and families so that they can make an informed choice about the treatment. Additionally, the research could provide much needed information to define the role of psychological input in the patient selection and evaluation process of the surgery. It is hoped that information gained from the research can improve the support provided by healthcare teams and surgical teams to meet the psychological and physical needs of patients. The research will also be part of my Doctoral Thesis which will go towards my qualification as a Clinical Psychologist.

***Why have I been invited?***

I am interested in your experience of spinal cord stimulation surgery and your chronic neuropathic pain. I have contacted you because you have recently had spinal cord stimulation surgery. I am hoping to interview a maximum of ten people to complete the research.

***Do I have to take part?***

It is up to you to decide, the research is voluntary. If you do not want to be included in the research your regular treatment at the hospital will not be affected in any way. If you decide to take part, you are still free to change your mind and withdraw from the research up until one week after the interview. If you choose to withdraw, you do not need to provide a reason and this will not affect the standard of care you receive.

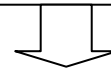
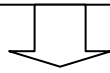
***What will happen to me if I take part?***

You will be asked to take part in a semi-structured interview. This interview will last for around one hour. The interview will be audio recorded using a Dictaphone. The interview is recorded because it would be difficult to write detailed notes on what you were saying and listen to your experience at the same time. Therefore, by recording the interview I can write up the interview word for word and use this to help me complete the analysis. The interview recording will be stored on a university computer and will be password protected. I will be the only person to access this data. Following this, the data will be copied on to an encrypted data stick. This will be stored in a locked filing cabinet at the University of Nottingham. All data files will be stored anonymously, therefore identification numbers will be used, not your name. The data obtained from the interview will only be viewed in full by myself and my academic supervisor. On submission of the Doctoral thesis, I will use quotes directly from the data in the analysis. However, I will make sure you cannot be identified from these quotes.

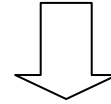
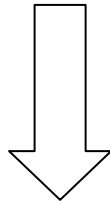
After considering the information on this sheet, I am happy to answer any questions you have about the research. You can contact me on my research study mobile on 07583419942 or via email if preferred at [lwamt1@nottingham.ac.uk](mailto:lwamt1@nottingham.ac.uk).

I have included the following diagram to demonstrate what can happen now:

You have already received the information pack detailing the purpose of the research and what your role would be

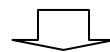


**Option 1:** I would like to discuss the research      **Option 2:** I do not wish to take part



If you do not make contact with me in two weeks, it will be noted that you do not wish to take part in the research. This will not affect your standard of care.

Please contact me by telephone or email and I can provide further information about the research and answer any questions.



If you decide to take part in the research, you can have the interview at your neuromodulation clinic appointment at the Department of Neurosurgery, [REDACTED] or in your own home.  
If you would like to be interviewed at your neuromodulation appointment, please inform me of any seating aids (e.g. wheelchairs/ cushions) you may want to bring to make the interview more comfortable.



I will call you the day before the interview to check the time, date and location of the interview are ok and you still want to take part



At the start of the interview, I will ask you to sign a consent form and ask you some basic questions about yourself and your previous treatment for your chronic neuropathic pain.  
Then I will start the interview and recording. After the interview, you will be given the opportunity to ask any questions and provide feedback on your involvement in the research.



If you would like a summary of the research when it is completed, you can sign a request form and it will be sent to you when the study is completed.

### ***Expenses and payments***

The interview will be held at the Department of Neurosurgery in the [REDACTED] when you go for your neuromodulation clinic appointment 4-8 months after your surgery. Alternatively, the interview can be held in the comfort of your own home. This way you are not making any extra journeys to be part of the research, therefore no expenses or payments will be offered.

### ***What are the potential disadvantages and risks of taking part?***

The research is interested in exploring your experience of the treatment journey of spinal cord stimulation surgery; therefore there is no definite interview schedule. The interview will follow a set of questions; prompts related to questions will be determined by how you answer the questions. Therefore, the interview could potentially bring about sensitive topics of conversation. In the event that you feel like you need to take a break from the interview or would like to stop the recording, this can be done. Information leaflets of support services will be available on the interview day such as the Samaritans National Helpline (08457 90 90 90) and advice of other support services will be provided if required.

Although, the interview will only be for an hour, the whole process will involve being seated for a couple of hours in total. Therefore to make this as comfortable as possible please bring any seating aids (e.g. cushions) and feel free to get up, stretch, walk around at any point during the interview. Also, we can take a break should you wish to adjust your stimulator for pain relief.

### ***What are the possible benefits of taking part?***

I cannot say that the research will help you. However, I hope that by discussing your experiences, this will benefit others who are making the decision about this surgical procedure and also provide information for healthcare providers.



***What will happen if I don't want to carry on with the study?***

Your participation is voluntary and you are free to withdraw up to one week after the interview, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

***What if there is a problem?***

If you have a concern about any aspect of the research, please feel free to contact me on my research study mobile on 07583419942 and I will do my best to answer your questions. Alternatively, you can contact my clinical supervisor **Jamie Macniven** on [REDACTED]. If you remain unhappy and wish to complain, you can do this through the NHS Complaints Procedure for [REDACTED] by contacting [REDACTED] on [REDACTED].

***Will my taking part in this study be confidential?***

Yes. If you join the research study, I have a duty of confidentiality to you as a research participant and I will do my best to meet this duty by following ethical and legal practice. I will store any information with your name on (e.g. consent form and a sheet matching you to a participant identification number and pseudonym) in a locked filing cabinet at the University of Nottingham. All other data will be anonymised using the above identification number so that you are not recognisable (e.g. demographic information sheet, recording of the interview and write up of the interview). These documents will also be stored in a locked filing cabinet. Your personal contact details will be destroyed after it is no longer necessary to contact you.

***What will happen to the results of the research study?***

The results of the research study will be written up as part of my Doctoral thesis with the aim of a publication in relevant journals. It may also be presented at conferences related to spinal cord

stimulation surgery. At the end of the interview you will be asked if you would like to receive a summary of the research study. You will not be identified in any report, publication or presentation.

***Who is organising and funding the research?***

The research study is being sponsored and funded by the University of Nottingham.

***Who has reviewed the study?***

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your interest. This study has been reviewed and given favourable opinion by Leicestershire, Northamptonshire and Rutland Research Ethics Committee 1.

***Further information and contact details***

For some general information about research, please refer to the National Research Ethics Service website:  
<http://www.nres.npsa.nhs.uk>.

If you would like more specific information about the research project or if you require any information or advice on whether or not you should participate in the study, please feel free to contact me on my research study mobile on 07583419942 or email at [lwamt1@nottingham.ac.uk](mailto:lwamt1@nottingham.ac.uk).

Alternatively you can speak to a member of your health care team, your GP or to the Patient Advice and Liaison Service on [REDACTED].

**Study Coordinator**

Anna Turner  
Institute of Work, Health and Organisations,  
University of Nottingham  
Jubilee Campus,  
Wollaton Road,  
Nottingham  
NG8 1BB  
Research Study Mobile:  
07583419942

[lwaxamt1@nottingham.ac.uk](mailto:lwaxamt1@nottingham.ac.uk)

**Chief Investigator**

Prof. Nadina Lincoln  
Address same as  
study coordinator

Tel: 0115 9515315

[nadina.lincoln@nottingham.ac.uk](mailto:nadina.lincoln@nottingham.ac.uk)

## Appendix M: A: Minor amendment letter

### Leicestershire, Northamptonshire & Rutland Research Ethics Committee 1

Tel: [REDACTED]

Fax: [REDACTED]

16 December 2010

Ms Anna Turner  
Principal Investigator  
I-WHO, International House  
B Floor  
Jubilee Campus  
Nottingham  
NG8 1BB

Dear Ms Turner,

**Study title:**

**Spinal Cord Stimulation Surgery for Chronic  
Neuropathic Pain: The Psychological Experience  
of the Treatment Journey**

**REC reference:** 10/H0406/66

**Protocol number:** 10063

**Amendment number:** 1

**Amendment date:** 03 December 2010

Thank you for your letter of 03 December 2010, notifying the Committee of the above amendment. The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

**Documents received**

The documents received were as follows:

Document	Version	Date
Notification of a Minor Amendment - additional letter clarifying researcher's email address	1	03 December 2010
Letter to be sent about email	1.0	03 December 2010

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**10/H0406/66:** Please quote this number on all correspondence

Yours sincerely,

**[REDACTED]**  
**Committee Co-ordinator**

E-mail: [REDACTED]

Copy to: [REDACTED] *Research Innovation Services*

*R&D office for NHS care organisation at lead site – [REDACTED]*

*Professor Nadina Lincoln – Chief Investigator*

## Appendix M: B: R&D minor amendment letter



Please reply to:

Research and Development



Telephone:

Fax:

E-mail:



Miss Anna Turner  
I-WHO University of Nottingham  
International House  
B Floor, Jubilee Campus  
Wollaton Road  
NG8 1BB

22 December 2010

Dear Miss Turner

ID: 10PT004

**Spinal Cord Stimulation Surgery for chronic Neuropathic Pain: The Psychological Experience of the Treatment Journey**

Thank you for your letter, informing R&D of the following amendments:

- REC letter for minor amendment dated 16/12/10
- Letter to be sent about email version 1.0 dated 03/12/10

The amendment has been given R&D approval, however, you may be contacted in due course if we wish to re-visit the original costings attached to the study.

Yours sincerely

  
Research Manager (Governance)

## **Appendix M: C: Letter clarifying email address**

Spinal Cord Stimulation Surgery for Chronic Neuropathic Pain:  
The Psychological Experience of the Treatment Journey

Dear

The Department of Neurosurgery at the [REDACTED]  
[REDACTED] previously sent you an information pack on behalf Anna  
Turner for the above research. However, it has come to our attention  
that there has been some confusion over the email address.

If you were interested in taking part in the study, the email address is  
all in lower case [lwamt1@nottingham.ac.uk](mailto:lwamt1@nottingham.ac.uk), the first letter is a lower  
case L. Alternatively she can be contacted on her research mobile on  
07583419942 and she will get back to you as soon as possible.

Thank you for your time,  
Kind Regards,

[REDACTED] Consultant Neurosurgeon  
Secretary [REDACTED]  
[REDACTED]

## Appendix N: A: Substantial amendment letter



### *National Research Ethics Service*

Leicestershire, Northamptonshire & Rutland Research Ethics Committee 1



08 February 2011

Professor Nadina Lincoln  
Professor in Clinical Psychology  
University of Nottingham  
Room B19, International House  
Institute of Work Health and Organisations  
Jubilee Campus  
Nottingham  
NG8 1BB

Dear Professor Lincoln,

**Study title:** Spinal Cord Stimulation Surgery for Chronic Neuropathic Pain: The Psychological Experience of the Treatment Journey  
**REC reference:** 10/H0406/66  
**Protocol number:** 10063  
**Amendment number:** 2  
**Amendment date:** 24 January 2011

The above amendment was reviewed at the meeting of the Sub-Committee held on 04 February 2011.

#### **Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

#### **Approved documents**

The documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	3.0	03 December 2010
Notice of Substantial Amendment (non-CTIMPs) - change to inclusion criteria	2	24 January 2011

#### **Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

This Research Ethics Committee is an advisory committee to East Midlands Strategic Health Authority  
*The National Research Ethics Service (NRES) represents the NRES Directorate within the  
National Patient Safety Agency and Research Ethics Committees in England*

WPH 1370



### R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

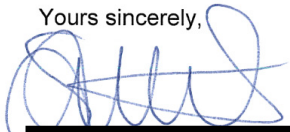
### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

10/H0406/66:

Please quote this number on all correspondence

Yours sincerely,



Committee Co-ordinator

E-mail:

Enclosures:

List of names and professions of members who took part in the review

Copy to:

R&D office for NHS care organisation at lead site – 

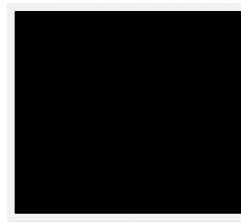
Miss Anna Turner - Student

## Appendix N: B: R&D Substantial amendment letter



Please reply to:

Telephone:  
Fax:  
E-mail:



Miss Anna Turner  
I-WHO University of Nottingham  
International House  
B Floor, Jubilee Campus  
Wollaton Road  
NG8 1BB

16 February 2011

Dear Miss Turner

ID: 10PT004

**Spinal Cord Stimulation Surgery for chronic Neuropathic Pain: The Psychological Experience of the Treatment Journey**

Thank you for your letter, informing R&D of the following amendments:

- Protocol version 3.0 dated 03/12/10
- Amendment form dated 24/01/11

The amendment has been given R&D approval, however, you may be contacted in due course if we wish to re-visit the original costings attached to the study.

Yours sincerely

  
  
 Research Manager (Governance)

## Appendix O: Written consent form

### CONSENT FORM

(Final version 1.0: 29.07.2010)

Spinal Cord Stimulation Surgery for Chronic Neuropathic Pain:  
The Psychological Experience of the Treatment Journey

**REC ref:** 10/H0406/66

**Name of Researcher:** Anna Turner

**Name of Participant:**

**Please initial box**

1. I confirm I have read and understand the information sheet final version 1.0 dated 29.07.2010 for the above research. I confirm I have had the opportunity to consider this information and ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw up to one week following the interview, without providing a reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected cannot be erased. ☐
3. I understand that data collected in the research may be viewed by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in the study. I give permission for these individuals to have access to data and to collect, store, analyse and publish information obtained from my participation in this research. I understand that my personal details will be kept confidential. ☐
4. I understand the interview will be recorded and that anonymous direct quotes from the interview may be used in the research reports. ☐
5. I agree to take part in the above research. ☐

**Name of Participant**

**Date**

**Signature**

**Name of Principal Investigator**

**Date**

**Signature**

Three copies will be produced: 1 for the participant, 1 for the research notes and 1 for the medical notes

## **Appendix P: Demographic information sheet**

### **DEMOGRAPHIC INFORMATION**

#### Spinal Cord Stimulation Surgery for Chronic Neuropathic Pain: The Psychological Experience of the Treatment Journey

Participant number: \_\_\_\_\_

Gender: \_\_\_\_\_ M / F

Age: \_\_\_\_\_ years

Ethnicity: \_\_\_\_\_

Date of Birth: \_\_\_\_\_

Location of pain: \_\_\_\_\_

Diagnosis: \_\_\_\_\_

Length of time experienced pain: \_\_\_\_\_

Previous surgery: \_\_\_\_\_

Medication: \_\_\_\_\_

Previous/current mental health difficulties: \_\_\_\_\_

Previous psychological contact: \_\_\_\_\_

Date of SCS surgery: \_\_\_\_\_

## Appendix Q: Study request form

### STUDY SUMMARY REQUEST

Spinal Cord Stimulation Surgery for Chronic Neuropathic Pain: The  
Psychological Experience of the Treatment Journey

I \_\_\_\_\_

(NAME)

would like to receive a summary of the research when complete.

**Please send this to me by:**

Post

---

---

---

(ADDRESS)

Email

---

## Appendix R: Annual ethics report letter

### NRES Committee East Midlands - Leicester

[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]

09 September 2011

Prof. Nadina Lincoln  
University of Nottingham  
Jubilee Campus  
Nottingham  
NG8 1BB

Dear Prof Lincoln

<b>Study title:</b>	<b>Spinal Cord Stimulation Surgery for Chronic Neuropathic Pain: The Psychological Experience of the Treatment Journey</b>
<b>REC reference:</b>	<b>10/H0406/66</b>
<b>Protocol number:</b>	<b>10063</b>

Thank you for sending the progress report for the above study dated 08 September 2011. The report will be reviewed by the Chair of the Research Ethics Committee, and I will let you know if any further information is requested.

The favourable ethical opinion for the study continues to apply for the duration of the research.

<b>10/H0406/66: number on all correspondence</b>	<b>Please quote this</b>
------------------------------------------------------	--------------------------

Yours sincerely

[Redacted]  
**Administrative Assistant**

E-mail: [Redacted]

Copy to: Mr [Redacted],  
[Redacted]

## **Appendix S: Diary extract following interview with Pete**

'....I feel exhausted after this interview. I also feel sad for Pete. He has had a long and testing journey and now he is trying to accept life as it is. I was struck by how much he appreciated talking about his experiences and his suggestion that this may change the way he thinks about his stimulator. The reason why I say this is, he had this demeanour, this way about him, I don't know like there was this underlying anger and a desperate disappointment. It seemed he did not want to talk too explicitly about his disappointment, but alluded to it throughout, maybe in fear of being seen as ungrateful. He did stress he did not want to come across as ungrateful. Always feeling he has to manage how he comes across, that must be tiring in itself. I guess I was just surprised at how relaxed he appeared at the end, it was almost like he just wanted to be listened to, he wanted to talk about how the stimulator hadn't met his expectations, how he felt unprepared but feared how others would judge that'.

## Appendix T: A: Extract of exploratory coding for Pete (Descriptive, linguistic and Conceptual)

Line	Original Transcript	Exploratory Comments
1	R: Ok, so to begin with then, can you describe what life was like before your	
2	surgery for me?	
3	I: Right (pause), prior to the-e, I, I don't know if y-you realise I, I was a police	Police officer. Job role. Long time period – 20 years.
4	officer for 20 years	
5	R: Oh right	
6	I: Erm, during that time, you've got to be fairly fit, you've got to keep yourself	Perception must be fit and active for job role – did variety of sports. 'You've got
7	active so I use to play squash, golf, er as I said I use to walk (mentioned prior to	to' – 'got to keep' = rule? Important to him, his perception of what a police officer
8	interview), go walking 8-8, 9 miles a day was a good day out for me and I was	should be?
9	pretty active, erm, in 1992, I was assaulted whilst at work, erm, and ended up	Previously an active person.
10	being head butted which forced me, my neck back over a kerb, on th' floor,	
11	caused damage to er, i-it's cracked a vertebrae in the neck and ruptured the	Assaulted at work and cracked vertebrae in neck.
12	discs either side. As a result of that, I had a lot of head pain, a lot of er pain	A lot of pain and off work. Repetition 'a lot' to emphasise pain severity. Negative
13	down both arms, er, I was off work for quite a while, er, I got very depressed,	emotions, mood and behaviour. Listed these off quickly.
14	very anxious, very aggressive.	
15	R: Humm	
16	I: Er, and that's-that all comes out becos you realise, you thinking to, you sit	Process of thinking about assault - What he failed to do to prevent it.
17	down, you think to yourself, could I have done more to prevent this, you know	Rumination?
18	what's happened, and y-your angry with yourself and this depression, i-it's hard	Anger at self
19	to get out of, but eventually, I-I did eventually get out of it, and I returned back to	Depression. Rumination contribute to depression, how did he get out of it?
20	work, and er, but I wasn't allowed to go back out on the streets, the-the police	Change in tone – higher pitch from eventually. 'Eventually' - suggesting time
21	surgeon said you know, if at any time you might get a pull then you'd end up	before getting out of it. 'Wasn't allowed' - No choice, no control over change in
22	being paralysed, so.	job role. Would he have wanted to go back to his old job role, what did this mean
23	R: Yeah	to him? Vulnerability 'a pull then...paralysed'. Repetition: 'Wasn't allowed' no
24	I: So I wasn't allowed, so I had to change my life style, I'd got my (cough), my	choice, no control? Adapted lifestyle. Career 'planned' (past tense) – valued,
25	career planned out, that this is the route I'm gona take and this is where I'm	worked towards. 'Going to go' – (future tense) more plans? 'Suddenly' - speed of
26	going to go, but, that suddenly came to a halt.	change. Career plans stopped by assault. Disruption to anticipated future self.
27	R: Humm	Repetition of having to change lifestyle – 'totally' adding emphasis. Change.
28	I: You know, you have to change your life style totally (sniffs), which I did, er	Time frame.
29	(inhales), unfortunately 7 years later they made the decision that I couldn't do the	'They made the decision' – no control, not part of decision making? – Medically
30	job anymore and I was medically retired.	retired..



## **Appendix T: B: Extract from reflective diary on exploratory coding for second transcript - Pete**

‘....Given my natural tendency to be attracted towards structure, I have found the guidelines useful. However I do find myself ‘checking in’ regularly with the book. It helps me focus on the main task, to stay close to the data, yet making sure I attend to the conceptual aspects of the transcript. However, I am hoping to become a bit more flexible as I continue coding’.

‘.... This assault screams vulnerability to me and a loss of control. I find myself reflecting on the fact he was attacked at work, doing something he valued. I’m thinking about times when I have felt vulnerable, I can’t help but think about what it would be like for a man though, especially given his role in the police seems so important to him. I guess the event itself is irrelevant to my research but the impact of the consequences of this event, the loss and lack of control are central...I sense an underlying tone of anger, is this about the injustice of what happened to him or is it this the aggressive self he refers to? Is it his pain impacting on his emotions? Why did I not ask him what he meant by aggressive, I really want to know - as in his demeanour? Or, as in his actions? I had to jot this down, as it was a temporary distraction from attending to the data. I have come to value the use of this reflective diary as it helps me refocus so I stick closely to the data and don’t run away too much with my thoughts’.

## Appendix U: A: Identifying initial themes in Pete's transcript

Initial theme	Line	Original Transcript	Exploratory Comments
Significant work role	1 2 3 4	R: <i>Ok, so to begin with then, can you describe what life was like before your surgery for me?</i> I: Right (pause), prior to the-e, I, I don't know if y-you realise I, I was a police officer for 20 years	Police officer. Job role. Long time period – 20 years.
Loss of active self	5 6 7	R: <i>Oh right</i> I: Erm, during that time, you've got to be fairly fit, you've got to keep yourself active so I use to play squash, golf, er as I said I use to walk	Perception must be fit and active for job role – did variety of sports. 'You've got to' – 'got to keep' = rule? Important to him, his perception of what a police officer should be? Previously an active person.
Origin of initial pain	8 9 10	(mentioned prior to interview), go walking 8-8, 9 miles a day was a good day out for me and I was pretty active, erm, in 1992, I was assaulted whilst at work, erm, and ended up being head butted which forced me, my neck	
Negative impact of pain on emotions	11 12 13 14	back over a kerb, on th' floor, caused damage to er, i-it's cracked a vertebrae in the neck and ruptured the discs either side. As a result of that, I had a lot of head pain, a lot of er pain down both arms, er, I was off work for quite a while, er, I got very depressed, very anxious, very aggressive.	Assaulted at work and cracked vertebrae in neck. A lot of pain and off work. Repetition 'a lot' to emphasise pain severity. Negative emotions, mood and behaviour. Listed these off quickly.
Aggressive	15	R: <i>Humm</i>	
Ruminative thinking	16 17 18	I: Er, and that's-that all comes out becous you realise, you thinking to, you sit down, you think to yourself, could I have done more to prevent this, you know what's happened, and y-your angry with yourself and this depression,	Process of thinking about assault - What he failed to do to prevent it. Rumination? Anger at self. Depression. Rumination contribute to depression, how did he get out of it? Change in tone – higher pitch from eventually.
Anger at self	19 20 21 22 23	i-it's hard to get out of, but eventually, I-I did eventually get out of it, and I returned back to work, and er, but I wasn't allowed to go back out on the streets, the-the police surgeon said you know, if at any time you might get a pull then you'd end up being paralysed, so. R: <i>Yeah</i>	'Eventually' - suggesting time before getting out of it. 'Wasn't allowed' - No choice, no control over change in job role. Would he have wanted to go back to his old job role, what did this mean to him? Vulnerability 'a pull then...paralysed'. Repetition: 'Wasn't allowed' no choice, no control? Adapted lifestyle. Career 'planned' (past tense) – valued, worked towards. 'Going to go' – (future tense) more plans? 'Suddenly' - speed of change. Career plans stopped by assault. Disruption to anticipated future self.
Physically vulnerable	24 25 26 27	I: So I wasn't allowed, so I had to change my life style, I'd got my (cough), my career planned out, that this is the route I'm gona take and this is where I'm going to go, but, that suddenly came to a halt. R: <i>Humm</i>	Repetition of having to change lifestyle – 'totally' adding emphasis. Change. Time frame. 'They made the decision' – no control, not part of decision making? – Medically retired..
Lack of choice	28 29 30	I: You know, you have to change your life style totally (sniffs), which I did, er (inhales), unfortunately 7 years later they made the decision that I couldn't do the job anymore and I was medically retired.	
Disruption of aspirations			
Lack of control of decision making			

## **Appendix U: B: Reflective diary extract on identifying initial themes**

‘....So at this stage I need to write pithy statements, but I am struggling to do that. It is hard trying to capture the understanding interpretatively in a short statement. Also I guess I am aware of my audience, I don’t think it will be helpful using too abstract statements like I have read in some IPA studies...I am mindful of this, but I equally want to remain true to the IPA approach’.

## Appendix V: Abridged table of numeration analysis for Pete

Initial Theme	Frequency
Acceptance II	2
Adaptation to physical restrictions II	2
<b>Aggressive II</b>	2
Anger at professionals	1
<b>Anger at self</b>	1
Behavioural modifications III	3
Behavioural modifications to SCS	1
Cheated	1
Chronicity of pain	1
Cognitive modifications	1
Conflict: Grateful vs disappointment II	2
Containing undesirable self	1
Decreased mobility	1
Dependence (others II/stick)	3
Depleting motivation	1
Depression cycle II	2
Desire to be alone II	2
<b>Disruption of aspirations</b>	1
Environment modifications	1
Expectations II/faith in SCS	3
Expectations not met	1
External locus of control II	2
Group identity	1
Hope	1
Hopelessness IIII	4
Increased disability	1
Job as a commitment	1
<b>Lack of choice II</b>	2
Lack of communication III	3

### Reflective diary extract:

‘....So I find the numeration analysis interesting as it has drawn my attention to the negativity present within this transcript, particularly the negative emotions and his efforts to cope.’

## Appendix W: Theme table for Pete

Super-ordinate theme	Initial theme
Battling through the system	Anger at professionals Back to square one Lack of communication Lack of consideration from hospital staff No mention of operation risks Past treatment failures Persistence with various treatments Process of diagnosis
Managing expectations	Expectations not met Expectations of SCS panel Faith in SCS Hope Painless mobility of trial Past expectations led to disappointment Selling self to get SCS
Loss of identities	Group identity <b>Job as a commitment</b> Loss of active self Loss of job identity Loss of non-pain self <b>Significance of work role</b>
Managing the unwanted pain identity	<b>Aggressive</b> <b>Anger at self</b> Desire to be alone Lack of control of self Miserable Pain severity Persistence of pain Personality change Rejection of dependence/others Self –focused Undesirable/unwanted self Visibility of disability
Impact of non-able body	Decreased mobility Restricted movement / Restrictions of immobility Restrictions of medication Physical restrictions Dependent on other/ stick Social exclusion/isolation/withdrawal Increased disability Adaptations to physical restrictions

Impact of pain	Behavioural modifications Cognitive modifications Disruption of aspirations Environment modifications Negative impact of medication on memory <b>Negative impact of pain on emotions</b> Pain Impact on Everything Planning Relationship adaptation
Battle to cope with depressive symptoms	Cycle of depression Hopelessness Lacked opportunity to discuss problems with HCPs Learning process Loss of motivation Loss of purpose <b>Ruminative thinking</b> Sense of release from expressing experience Significance of a sense of purpose Significance of re-establishing identities Significant support Struggle to keep going Wife protector and motivator Worrying about future
Conflict of SCS: Grateful Vs Disappointment	Acceptance Adaptation to SCS Behavioural modifications to SCS Change from pain to squeezing sensation Coping with side effects/ Not prepared for side effects Increased disability Last hope Loss of control of leg No change Querying disappointment
Powerlessness	Cheated External locus of control <b>Lack of choice</b> <b>Lack of control of decision making</b> Powerless

**NB: BOLD text shows the audit trail from the initial themes in appendix U.**

### Appendix X: Abridged recurrent theme table

Super-ordinate theme	Sub-ordinate theme	Participant (pp)							No.of pps
		Sally	Pete	Nicole	Mike	Jack	Maya	Sarah	
Transitions of the self	Loss of identities	✓	✓	✓	✓	✓	✓	✓	7
	Managing the unwanted pain identity	✓	✓	✓	✓	✓	✓	✓	7
Diminished control and coping	Impact of pain And the non-able body	✓	✓	✓	✓	✓	✓	✓	7
	Coping with symptoms of depression	✓	✓	✓	✓	✓		✓	6
	Battling the system and managing expectations	✓	✓	✓	✓	✓	✓	✓	7
	Multiple levels of powerlessness	✓	✓	✓		✓	✓	✓	6
Conflict of SCS	Positive change	✓		✓	✓	✓	✓	✓	6
	Disappointment, adaptations and acceptance		✓	✓	✓	✓	✓	✓	6

There were other themes, however they only applied to one or two participants transcripts and were not strong enough within the transcripts to be included in the analyses.

## **Appendix Y: Reflective diary extract on organising themes across transcripts**

'I am thinking on a higher level now to identify the overall commonalities alongside the more subtle similarities. I am struck by the divergences too. This is an exciting but equally overwhelming experience trying to make sense of such a vast amount of data. I have been grappling with this concept of powerlessness. It is making me feel powerless in trying to do it justice in the analysis! I feel it is inherent in every transcript and for some, it underlined their whole account. Yet, their powerlessness seems to have been experienced in so many different ways – in response to their pain, the stimulator, the system so how can I convey this. It's like similarity with a difference.'